**Appendix C: Characteristics of Ongoing Studies [ordered by study ID]**

**ACTRN12617001619336**

|  |  |
| --- | --- |
| Trial name or title | Reduction Of Chronic Post-surgical Pain with Ketamine - ROCKet Trial |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: Patients (18-85) with ASA 1-3 undergoing elective or expedited surgery and anaesthesia for abdominal surgery involving an expected skin incision at least 8cm in length and including open herniorraphy; non-cardiac thoracic surgery, including mastectomy and breast reconstruction surgery, and including all video-assisted thoracoscopic surgery; hip and knee joint arthroplasty and spinal surgery involving an expected skin incision at least 8cm; plan for postoperative opioid analgesia; planned hospital stay of at least one night post-operatively. |
| Target sample size | 4884 |
| Interventions | Ketamine or placebo dosage is intravenous 0.5 mg/kg bolus, followed by 0.125 mg/kg/hr intra-operatively, then 0.125 mg/kg/hr continued for up to 72 hours post-operatively. The initial bolus dose will be administered after induction and prior to surgical incision. |
| Outcomes | Primary outcome: The incidence of chronic post-surgical pain (CPSP) reported by the patient at telephone follow-up structured interview [12 months post-surgery]  Secondary outcomes: Incidence of CPSP 3 months’ post-surgery; Severity of CPSP 3 and 12 months post-surgery using the adapted modified brief pain inventory short form (mBPI-sf); Incidence of moderate CPSP 3 and 12 months post-surgery; Incidence and severity of neuropathic symptoms 3 and 12 months post-surgery; QoL using the EQ-5D-3L and mBPI-sf 3 and 12 months post-surgery; Severity of acute post-operative pain in the first 3 days; Quality of recovery from anaesthesia 1 day post-surgery; Length of hospital stay; Incidence of post-operative delirium; Incidence of adverse/side effects; Depression after surgery, assessed using Kessler Psychological Distress Scale (K-10); Perioperative and long term health expenditure measured using Medicare data [12 months]; Opioid and other analgesic consumption in the first 3 days. |
| Starting date | December 2017 |
| Contact information | Prof Philip Peyton, Austin Health, Department of Anaesthesia, +61402282398, [phil.peyton@austin.org.au](mailto:phil.peyton@austin.org.au) |
| Notes | This study is currently recruiting participants. Date of last participant enrolment is anticipated for December 31, 2021. Last verified December 13, 2019.  <https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12617001619336> |

**EudraCT-2017-004711-39**

|  |  |
| --- | --- |
| Trial name or title | Tramadol-paracetamol in spine surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (18-75), BMI 18-35 kg/m2, undergoing elective spine surgery. |
| Target sample size | 120 |
| Interventions | The participants will use tramadol-paracetamol 37.5mg or placebo as long as their postoperative pain is moderate to severe, on a numeric rating scale at rest 3/10 or higher and/or dynamic pain 5/10 or higher. The drugs will be used up to 5 days. A maximum of 20 tablets. |
| Outcomes | Primary outcome: To evaluate the patient satisfaction on analgesia efficacy of tramadol-paracetamol combination product for postoperative pain management in spine surgery.  Secondary outcome(s): Need for rescue analgesia and the amount of pain during the first postoperative week, adverse effects, pain and need for analgesics at 12 months after surgery. |
| Starting date | Not reported. Date of Ethics Committee Opinion 2018-04-10 |
| Contact information | Merja Kokki, Kuopio University Hospital, Finland, [merja.kokki@kuh.fi](mailto:merja.kokki@kuh.fi) |
| Notes | The status of this study is ongoing. Last verified December 6, 2019.  <https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-004711-39/FI> |

**ISRCTN63614165**

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| --- | --- |
| Trial name or title | Gabapentin in post-surgery pain |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (>18) undergoing non-emergency surgery, cardiac (surgery on the heart and great vessels carried out via midline sternotomy), thoracic surgery (surgery on the lungs and surrounding tissues), abdominal (open or laparoscopic surgery within the abdominal cavity). |
| Target sample size | 1500 |
| Interventions | Intervention group: Participants receive gabapentin 600 mg given preoperatively with the patient's premedication and 600 mg/day (300 mg in the morning and 300 mg in the evening) given postoperatively for two days.  Control group: Participants receive a placebo which will be taken at the same time points. |
| Outcomes | Primary outcome: Time from start of surgery to hospital discharge is measured by reviewing participant hospital notes at discharge.  Secondary outcomes: 1. Opioid consumption; 2. Acute post-operative pain; 3. Adverse health events up to 4mo and on-going pain; 4. HRQoL measured using the EQ-5D 5 and Short-form (SF) 12 at 4 weeks and 4mo; 5. Resource use up to 4mo; 6. Chronic pain using the brief pain inventory (BPI) baseline and 4mo |
| Starting date | June 2017 |
| Contact information | Professor Chris Rogers, University of Bristol, [Chris.Rogers@bristol.ac.uk](mailto:Chris.Rogers@bristol.ac.uk) |
| Notes | This study is currently recruiting participants. Recruitment ends 01/08/2020. Last verified December 6, 2019.  <http://www.isrctn.com/ISRCTN63614165> |

**NCT00583869**

|  |  |
| --- | --- |
| Trial name or title | Role of Pregabalin in Treatment of Post-Op Pain in Fracture Patients (LYRICA) |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (19-70) with fractures requiring operative treatment during a single operative episode  Exclusion criteria: history of opioid abuse/misuse; contraindications to pregabalin or narcotic analgesics; closed head injury; psychiatric illness requiring medical treatment; surgery for other injuries (splenectomy,  etc); history of seizures requiring current anticonvulsant therapy |
| Target sample size | 150 (Actual enrollment: 86) |
| Interventions | Placebo group: Two hours before surgery, patients will receive 75mg of pregabalin. Patients will be placed on a patient-controlled anesthesia pump (PCA) for 24 hours. On post-operative day one, the patients will be switched to oral oxycodone as needed with supplementation with IV Demerol for breakthrough pain. In addition, patients will receive a placebo PO BID or pregabalin 75 mg or pregabalin 150 mg beginning on the day of surgery until discharge. Upon discharge, the patient will be given study medication (placebo PO BID or pregabalin). Rescue medications will be allowed during the study (including post-operative and outpatient periods). Outpatient rescue medications will consist of hydrocodone/APAP 7.5mg PO Q6H PRN |
| Outcomes | Primary outcome: Amount of pain medication in morphine equivalent units used during the hospitalization  Secondary outcome measures: pain scores at 3 months |
| Starting date | May 2007 |
| Contact information | David A. Volgas, MD, Associate Professor of Surgery, The University of Alabama at Birmingham |
| Notes | This study has been completed. First received on December 21, 2007. Last update posted on January 7, 2014. Actual study completion date: August 2009.  <https://clinicaltrials.gov/ct2/show/NCT00583869> |

**NCT00631891**

|  |  |
| --- | --- |
| Trial name or title | Pregabalin in Treating Pain in Women Undergoing Mastectomy or Lumpectomy |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Patients (ASA I-III) undergoing unilateral modified radical mastectomy or lumpectomy with axillary node dissection. Exclusion criteria: allergy to study drugs, drug/alcohol abuse; kidney failure; concurrent use of other analgesics |
| Target sample size | 65 (Actual enrollment: 80) |
| Interventions | Oral placebo or pregabalin 1-2 hours prior to surgery, at 12 hours after surgery, and then twice daily for 14 days |
| Outcomes | Primary outcome measures: pain scores at 3 months; PCA morphine consumption; side effects profile; and modified Brief Pain Inventory-short form |
| Starting date | December 2006 |
| Contact information | Babatunde Ogunnaike, Simmons Comprehensive Cancer Center at University of Texas Southwestern Medical Center - Dallas |
| Notes | This study has been completed. First received on June 27, 2011. Last update posted on August 12, 2014.  Actual study completion date: June 2013.  <https://clinicaltrials.gov/ct2/show/NCT00631891> |

**NCT00663962**

|  |  |
| --- | --- |
| Trial name or title | Pregabalin and Post-thoracotomy Pain |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: patients (18-75; ASA I-III) undergoing elective thoracotomy (ET) or video assisted thoracotomy (VAT)  Exclusion criteria: intolerance to study drugs; Contraindication to thoracic epidural placement; Renal insufficiency (serum creatinine > 1.5 x upper limit of normal); Body Mass Index > 40; surgery extending to the chest wall; alcohol abuse; chronic pain/analgesic use; History of congestive heart failure; Major psychiatric disorder; Insufficient safety data in a specific patient population; Pregnant or breastfeeding |
| Target sample size | 10 (Actual enrollment: 15) |
| Interventions | Pregabalin 150mg or 300 mg or placebo administered 1 hour prior to surgery and 12 hours after surgery, then continued BID until day 7 post-op |
| Outcomes | Primary outcome measures: The primary outcome measure for the final study will be the incidence of CPTPS at 2 months. [Time Frame: 2, 4, and 6 months] |
| Starting date | April 2008 |
| Contact information | Dr Jorge Enrique Zamora, Department of Anesthesiology, Queen’s University |
| Notes | This study has been completed. First received on April 18, 2008. Last update posted on February 29, 2016.  Actual study completion date: May 2009.  <https://clinicaltrials.gov/ct2/show/NCT00663962> |

**NCT00852683**

|  |  |
| --- | --- |
| Trial name or title | The Effects of Peri-Operative Pregabalin on Post-Operative Pain Following Breast Cancer Surgery With Axillary Node Dissection: A Pilot Study |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: patients (18-60), ASA I-III undergoing breast surgery with axillary dissection for the treatment of breast cancer  Exclusion criteria: persons with a history of allergy to gabapentin or pregabalin, morphine, NSAIDs, acetaminophen or oxycodone; pregnancy; Body Mass Index >40; liver or renal failure; chronic opioid users (30 mg per day of morphine equivalent); gabapentin or pregabalin users within 3months of surgery; persons with a history of drug abuse |
| Target sample size | 70 |
| Interventions | Participants will receive pregabalin (75 mg BID) or placebo (sugar pills) for BID for 14 days starting 1 hour before surgery |
| Outcomes | Primary Outcome Measures: numeric rating pain Score at rest and with movement 24 hours after surgery.  Secondary OutcomeMeasures: Incidence of chronic post-mastectomy pain at 3 months defined as persistent pain or discomfort not present prior to surgery and not present as a result of new or recurrent tumour growth |
| Starting date | May 2008 |
| Contact information | Peter MacDougall, MD. pcmacdou@gmail.com |
| Notes | This study has been completed. First received on March 28, 2008. Last updated on March 7, 2014.  Actual study completion date: December 2013.  <https://clinicaltrials.gov/ct2/show/NCT00852683> |

**NCT01022840**

|  |  |
| --- | --- |
| Trial name or title | The Preemptive Analgetic Potency of Low Dose S-Ketamine (Miniket) |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: adult patients (ASA I-III) scheduled for major abdominal surgery, suitable for PCA, with acceptable compliance for pain monitoring  Exclusion criteria: allergy to S-Ketamine, severe liver or kidney dysfunction, severe coronary disease, pregnancy, present or past psychotic disorders, addiction to alcohol or opioids |
| Target sample size | 60 |
| Interventions | 3 groups: placebo as saline solution, low dose ketamine and high dose ketamine |
| Outcomes | Primary Outcome Measures: postoperative opioid consumption [Time Frame: 1 year] |
| Starting date | February 2009 |
| Contact information | Andreas Sandner-Kiesling, MD (andreas.sandner@medunigraz.at) |
| Notes | This study has been completed. First received on November 21, 2009. Last update posted on October 2, 2012. Actual study completion date: September 2012.  <https://clinicaltrials.gov/ct2/show/NCT01022840>  Results published for early post-operative period (opioid consumption, pain levels, hyperalgesia at the incision site, and delirium scores 48 h postoperatively): Bornemann-Cimenti H, Wejbora M, Michaeli K, Edler A, Sandner-Kiesling A. The effects of minimal dose versus low-dose S-ketamine on opioid consumption, hyperalgesia, and postoperative delirium: a triple-blinded, randomized, active- and placebo-controlled clinical trial. Minerva Anestesiol 2016;82:1069-76 |

**NCT01082874**

|  |  |
| --- | --- |
| Trial name or title | PeriOperative ISchemic Evaluation-2 Trial (POISE-2) |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: Adults ( ≥45) undergoing non-cardiac surgery who are at risk of a perioperative cardiovascular event |
| Target sample size | 10000 (Actual enrollment: 10010) |
| Interventions | Study arms: Active Clonidine and Active ASA; Active Clonidine and Placebo ASA; Placebo Clonidine and Active ASA; Placebo Clonidine and Placebo ASA  Active Clonidine = Pre-op (goal 2-4 hours): 2 x 0.1mg oral tablets and transdermal patch (0.2 mg/day). Patch to be removed 72 hours post-op.  Active ASA = Pre-op (goal 2-4 hours): 2 x 100mg oral tablets. Post-op: patients ingest one tablet a day (100 mg ASA) for 7 days if patient was were taking ASA chronically prior to surgery or for 30 days if they were not chronically taking ASA prior to surgery  Placebo Clonidine: Pre-op (goal 2-4 hours): 2 oral placebo tablets and transdermal placebo patch. Patch to be removed 72 hours post-op.  Placebo ASA: Pre-op (goal 2-4 hours): 2 oral placebo tablets. Post-op: patients ingest one placebo tablet a day for 7 days if patient was were taking ASA chronically prior to surgery or for 30 days if they were not chronically taking ASA prior to surgery |
| Outcomes | Primary outcomes: Composite of All-cause Mortality and Nonfatal MI [Time Frame: 30 days, 1 Year]  Secondary outcomes: |
| Starting date | July 2010 |
| Contact information | Principal Investigator: P.J. Devereaux, MD, PhD, Population Health Research Institute  Study Chair: Salim Yusuf, DPhil, Population Health Research Institute |
| Notes | This study has been completed. First received on March 8, 2010. Last update posted on August 25, 2016.  Actual study completion date: January 2015.  <https://clinicaltrials.gov/ct2/show/NCT01082874> |

**NCT01359059**

|  |  |
| --- | --- |
| Trial name or title | Pre- Versus Post-incisional Pregabalin for Postoperative Pain Attenuation and Analgesics Spare in Orthopedic Oncologic Patients |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: ASA physical status I-III adult patients who will undergo bone with or without soft tissue cancer surgery type II and III under general or epidural anesthesia  Exclusion criteria: allergy to study drugs; chronic pain; psychiatric disorders; chronic use of centrally acting drugs of any sort, pregnancy |
| Target sample size | 80 |
| Interventions | Patients will receive 150 mg of pregabalin or placebo the evening before surgery and 1.5 hours before surgery and will undergo surgery under GA. A second cohort of patients will be randomized similarly but will undergo surgery under epidural analgesia. No other premedication will be administered to any patient. Post-operatively, patients who received preoperative pregabalin will be given placebo and vice versa at 2 hours after surgery. All patients will receive pregabalin 150 mg twice daily thereafter, BID postoperatively up to day 4 |
| Outcomes | Primary outcome measures: to assess the effects of the drug administered either pre-incisionally or postincisionally on the immediate and late setting (1- and 3 months); pain scores will be measured again 2 years after surgery |
| Starting date | June 2011 |
| Contact information | Avi A Weinbroum, Tel-Aviv Sourasky Medical Center |
| Notes | The recruitment status of this study is unknown because the information has not been verified recently. Last update posted June 2011 by Tel-Aviv Sourasky Medical Center. Recruitment status was: Not yet recruiting.  <https://clinicaltrials.gov/ct2/show/NCT01359059> |

**NCT01391858**

|  |  |
| --- | --- |
| Trial name or title | Postoperative Pain and Morphine Consumption After Mastectomy - Lyrica |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: 80 adult women (17 - 80) undergoing mastectomy. Exclusion criteria: those with known allergy to pregabalin or morphine and those with a history of alcohol abuse, chronic pain, history of daily intake of analgesics or steroids, and patients with impaired kidney function or diabetes mellitus |
| Target sample size | 65 (Actual enrollment: 80) |
| Interventions | Pregabalin 300 mg or matching placebos will be administered to each patient one to 2 hours before surgery followed by 150 mg BID during 2 weeks |
| Outcomes | Primary outcome measures: opioid Requirement at 14 days; IV-PCA morphine for rescue pain management in the immediate postoperative period and oral opioids after discontinuation of IV-PCA.  Secondary outcome measures: pain scores at 3 months |
| Starting date | December 2006 |
| Contact information | Babatunde Ogunnaike, MD, UT Southwestern Medical Center |
| Notes | This study has been completed. First received on June 27, 2011. Last update posted on August 12, 2014.  Actual study completion date: June 2013.  <https://clinicaltrials.gov/ct2/show/NCT01391858> |

**NCT01480765**

|  |  |
| --- | --- |
| Trial name or title | Preventing Pain After Heart Surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: Patients aged 18-80, undergoing sternotomy for elective cardiac surgery  Exclusion criteria: Previous sternotomy; preoperative renal failure; history of chronic non-anginal pain; chronic pain medication other than paracetamol and NSAIDs, concurrent use of oxycodone, lorazepam, or ethanol; concurrent use of any drugs for neuropathic pain (e.g. antiepileptics, antidepressants); allergy to study drugs; or pregnancy |
| Target sample size | 150 |
| Interventions | Pregabalin 150mg (2 hours) or matching placebos preoperatively and bid for 10 days, followed by dose reduction to 75mg twice daily for 2 days and finally to 50 mg twice daily for 2 days Drug; a third group will receive a placebo controlled Ketamine infusion 0.1mg/kg/hr for 48 hours postoperatively |
| Outcomes | Primary outcome measures: peri-incisional pain scores at 3 months, at rest and following 3 maximal coughs.  Secondary long-term outcome measures: Neuropathic pain score at 3 months using the Short form Leeds Assessment of Neuropathic Symptoms and Signs; Quality of Life at 3months; Preoperative and postoperative sensory test by Pressure algometry, tactile and pain detection thresholds with mechanical static stimulus using von Frey hairs and dynamic assessment of spatial and temporal summation |
| Starting date | November 2011 |
| Contact information | Sibtain Anwar, MA MB FRCA. sibtain.anwar@bartsandthelondon.nhs.uk |
| Notes | The recruitment status of this study is unknown because the information has not been verified recently. Last verified May 2012 by Barts & The London NHS Trust. Recruitment status was: Recruiting  <https://clinicaltrials.gov/ct2/show/NCT01480765> |

**NCT01789216**

|  |  |
| --- | --- |
| Trial name or title | Improving Pain Management and Long Term Outcomes Following High Energy Orthopedic Trauma (Pain Study) |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Patients 18-80 years old with multiple specified fractures requiring operative treatment with fixation. |
| Target sample size | 495 (Actual enrollment: 450) |
| Interventions | NSAID: oral 7.5 mg dose of Meloxicam twice daily, to be initiated on enrollment and continued for 14 days or through definitive fixation, whichever comes first. Patients will receive intravenous (IV) ketorolac dosing surrounding all operative procedures leading up to and including the definitive fixation. The oral protocol will be suspended while the patient is receiving medication from the perioperative protocol.  Gabapentinoid: oral 75mg dose of pregabalin twice daily, to be initiated on enrollment and continued for 14 days or through definitive fixation, whichever comes first.  Placebo: oral placebo pill twice daily for the first 14 days of the trial. A perioperative protocol will include an oral dose of placebo immediately prior to surgery and twice daily for 48 hours following any surgery, in addition to an intravenous dose of placebo immediately prior to surgery and every 6 hours for 48 hours following surgery. |
| Outcomes | Primary outcomes: Opioid Utilization, Persistent Pain and Surgery for non-union [Time Frame: 1 year]  Secondary outcomes: Pre and Post Surgical Pain Intensity; Length of Index Hospitalization; Adverse Effects and Complications; Functional Outcome; Generic Health Status; Depressive Symptoms; Post Traumatic Stress (PTSD); Medical Costs; Fracture Severity; Fracture Classification |
| Starting date | July 2013 |
| Contact information | Principal Investigators: Renan Castillo, PhD, Johns Hopkins Bloomberg School of Public Health and Lawrence Marsh, MD, University of Iowa Hospitals & Clinics |
| Notes | This study has been completed. First received on February 7, 2013. Last update posted on March 14, 2019.  Actual study completion date: December 31, 2018.  <https://clinicaltrials.gov/ct2/show/NCT01789216> |

**NCT01812057**

|  |  |
| --- | --- |
| Trial name or title | Dexamethasone for Post-cesarean Delivery Pain |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults, ASA class 1, 2 and 3, gestational age > 37 weeks scheduled for elective cesarean delivery under spinal or combined spinal epidural anesthesia  Exclusion Criteria: BMI > 45 kg/m2, Diabetes Mellitus (Type 1, 2 and gestational), mild or severe preeclampsia, history of intravenous drug or opioid abuse, previous history of chronic pain syndrome, history of opioid use in the past week, receipt of an antiemetic within 24 h prior to surgery, Non-English speaking |
| Target sample size | 104 (Actual enrollment: 53) |
| Interventions | Dexamethasone 8 mg IV given intraoperatively as a one-time dose.  Placebo: Sodium chloride 0.9% (5 ml) given IV intraoperatively as a one-time dose. |
| Outcomes | Primary outcome: Morphine Consumption at 24 Hours Post-op [Time Frame: 24 hours]  Secondary outcomes: Pain Scores at 2h, 24h, 48h; Time to Administration of First Rescue Analgesic Request; Cumulative Opioid Consumption at 24h, 48h; Incidence of Chronic Persistent Pain at 8 Weeks and 6 Months; Incidence of Intraoperative Nausea and Vomiting (IONV) and Post-operative Nausea and Vomiting (PONV) and need for Rescue Antiemetics; Incidence of Intraoperative and Postoperative Pruritus; Need for Intraoperative Analgesic Supplementation; Incidence of Wound Complications 24h; Blood Pressure Measurements |
| Starting date | December 2012 |
| Contact information | Principal Investigator: Terrence Allen, MD, Duke University |
| Notes | This study has been completed. First received on March 13, 2013. Last update posted on July 25, 2017.  Actual study completion date: September 21, 2016.  <https://clinicaltrials.gov/ct2/show/NCT01812057> |

**NCT01868633**

|  |  |
| --- | --- |
| Trial name or title | Dexamethasone for Post Cesarean Delivery Analgesia |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: ASA I-II physical status, non-laboring women, scheduled for elective cesarean section under spinal anesthesia  Exclusion Criteria: Contraindications to spinal anesthesia, allergy to study medication, patients with allergy to morphine, patients with uncontrolled hypertension, history of peptic ulcer disease, liver cirrhosis  diabetes mellitus, glaucoma, known IV drug abusers, patients with chronic pain or on long term opioids, patients administered steroids in the past week, women with fetuses having known congenital abnormalities, psychiatric illness such that they are unable to comprehend or participate in study questions, patients on antiviral medications or live virus vaccines. |
| Target sample size | 52 |
| Interventions | Dexamethasone: After cesarean delivery 8mg (2ml) of Dexamethasone given intraoperatively  Placebo: After cesarean delivery 2ml of placebo (Normal saline) drawn to mimic active drug given intraoperatively |
| Outcomes | Primary outcome: Postoperative Analgesia [Time Frame: 24 hours]  Secondary outcomes: Postoperative Pain at Rest and With Movement 24 Hours After Cesarean Delivery, Quality of Recovery [Time Frame: 48 hours]  Other outcomes: Number of Participants With Chronic Pain After Cesarean Delivery [Time Frame: 6 months] |
| Starting date | March 2013 |
| Contact information | Principal Investigator: Unyime Ituk, MD, University of Iowa |
| Notes | This study has been completed. First received on May 30, 2013. Last update posted on September 19, 2017.  Actual study completion date: May 2015.  <https://clinicaltrials.gov/ct2/show/NCT01868633> |

**NCT02271698**

|  |  |
| --- | --- |
| Trial name or title | Dexamethasone and Pain Following Total Knee Arthroplasty |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults 55 Years and older, ASA Physical Class 1-3,  BMI <40 kg/m2, scheduled to undergo unilateral total knee arthroplasty.  Exclusion Criteria: Revision surgery; Bilateral total knee arthroplasty; Unicompartmental knee arthroplasty; contraindication to regional anesthesia; contraindications or known drug interactions with dexamethasone; use of long-acting opioid medication within 3 days or any opioid medication within 24 hours; Body weight less than 50 kilograms; planned administration of another investigational product or procedure; abuse of illicit drug(s), prescription medicine(s), or alcohol within the past 2 years; uncontrolled anxiety, schizophrenia, or other psychiatric disorder; clinically significant disease or condition that may increase the risk of surgery or complicate the subject's postoperative course. |
| Target sample size | 40 (Actual enrollment: 45) |
| Interventions | Dexamethasone 6mg; Dexamethasone 12mg; Dexamethasone 24mg:  For each of the three experimental arms, iv dexamethasone at surgical incision and a repeat dose of dexamethasone 24h after incision.  Placebo: placebo injection of saline at surgical incision and a repeat placebo saline injection 24h after incision. |
| Outcomes | Primary outcomes: Change in Visual Analogue Pain Score [Time Frame: 6, 12, 18, 24, 36 hours after surgery]; Change in Opioid Consumption [Time Frame: 6, 12, 18, 24, 36 hours after surgery]  Secondary outcomes: Change in Functional Status as Measured by Western Ontario and McMaster Universities Osteoarthritis Index [Time Frame: 30 days, 3 and 6 months following surgery]; Change in Chronic Pain as Measured by Brief Pain Inventory Questionnaire [Time Frame: Baseline at enrollment, 3 months and 6 months after surgery]: Change in Functional Status as Measured by Brief Pain Inventory Questionnaire [Time Frame: Baseline at Enrollment, 3 and 6 months after surgery] |
| Starting date | December 2014 |
| Contact information | Principal Investigator: Stuart A Grant, MB ChB, Duke University |
| Notes | This study has been completed. First received on October 16, 2014. Last update posted on February 20, 2018.  Actual study completion date: July 2016.  <https://clinicaltrials.gov/ct2/show/NCT02271698> |

**NCT02306278**

|  |  |
| --- | --- |
| Trial name or title | The Effects of Gabapentin Premedication on Neurosurgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: Adults 18-65 years old, ASA physical status I or II, BMI<30, scheduled for elective craniotomy  Exclusion Criteria: History of mental or psychiatric disorders; Pregnant or lactating female; History of systemic malignant tumor or diabetes; Previously treated with this protocol or participated in another experimental study within previous 30 days; Suspected history of allergic reaction or intolerance to gabapentin or other anesthetic agents in this study; History of alcohol abuse and/or drug abuse |
| Target sample size | 100 (Actual enrollment: 122) |
| Interventions | Gabapentin 600mg orally at the night before operation and 2 hours before surgery, respectively  Placebo: vitamin capsules orally at the night before operation and 2 hours before surgery, respectively |
| Outcomes | Primary outcome: Pain in early postoperative period [Time Frame: 24 hour after extubation]  Secondary outcomes: Development of persistent pain and neuropathic pain [Time Frame: 3-mos and 6-mos after surgery]; Incidence of PONV [Time Frame: 1 hour,2 hours,1day,2 days after surgery] |
| Starting date | December 14, 2014 |
| Contact information | Study Chair: Ru Quan Han, chief, Beijing Tiantan Hospital |
| Notes | This study has been completed. First received on April 16, 2014. Last updated on October 16, 2017.  Actual study completion date: June 2016.  <https://clinicaltrials.gov/ct2/show/NCT02306278> |

**NCT02450214**

|  |  |
| --- | --- |
| Trial name or title | Intraoperative Ketamine and Magnesium Therapy for Control of Postoperative Pain After a Liposuction and Lipoabdominoplasty |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults, 18 years or older, ASA status 1 and 2, BMI 21-28 Kg/m2, scheduled for liposuction and lipoabdominoplasty.  Exclusion Criteria: Patients with surgeries added to the main proceedings, scheduled to tuck in Flor de Lis or Body Lift, History of use of analgesic drugs 48 hours before surgery, Peripheral central neurological diseases, Known allergy to medication use in this study (ketamine, magnesium, clindamycin and penicillin or other) |
| Target sample size | 60 (Actual enrollment: 63) |
| Interventions | Ketamine: 50 mL syringe will be infused at 0.3 mL/Kg in bolus and then 0.15 mL/Kg/h 100 mL flask will be infused at 1mL/Kg in bolus for 30 min and then 0.25mL/Kg/h  Ketamine + magnesium: 50 mL syringe will be infused at 0.3 mL/Kg in bolus and then 0.15 mL/Kg/h 100 mL flask will be infused at 1mL/Kg in bolus for 30 min and then 0.25mL/Kg/h  Placebo (Saline):50 mL syringe will be infused at 0.3 mL/Kg in bolus and then 0.15 mL/Kg/h 100 mL flask will be infused at 1mL/Kg in bolus for 30 min and then 0.25mL/Kg/h |
| Outcomes | Primary outcomes: Opioids consumption [12 h after surgery], Postoperative Pain [Time Frame: 2, 7, 14, 21, 45 and 90 days after surgery]  Secondary outcomes: Early postoperative pain [Time Frame: 0, 2, 4, 6, 12 and 24 h after surgery], Time to first request for supplemental analgesia [Time Frame: 1 day], Disability (Time delay in returning to work) [Time Frame: 90 days]; Postoperative Chronic Pain [Time Frame: Day after surgery, 7, 30 and 90 days after surgery] |
| Starting date | June 2015 |
| Contact information | Veronica Varas Vega, University of Chile |
| Notes | This study has been completed. First received on May 18, 2015. Last update posted on May 2, 2018.  Actual study completion date: July 2017.  <https://clinicaltrials.gov/ct2/show/NCT02450214> |

**NCT02511483**

|  |  |
| --- | --- |
| Trial name or title | Genetic Predictors of Analgesic Efficacy of Propranolol for Treating Postoperative Pain |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults, self-reported Caucasians, ASA physical status of I or II, scheduled for elective laparoscopic hemicolectomy surgery and willingness to agree with the Biobanking policy.  Exclusion Criteria: Uncontrolled medical or psychiatric conditions, severe mental impairment; History of major depressive disorder, psychotic disorder or schizophrenia, and/or manic episodes within the past year; Active alcoholism within the past 6 months; Psychoactive recreational drug abuse within the past 6 months including MDMA, Ketamine, hallucinogens such as LSD and/or sympathomimetics such as Cocaine; Inability to comprehend pain assessment; Pregnancy and/or breast-feeding; Known hypersensitivity to Beta Blockers or Opioids; Currently taking Propranolol, other hypotensive treatments, or opioids; asthma or reactive airway disease; cardiac arrhythmia, coronary artery disease, congestive heart failure; renal failure or dialysis; liver insufficiency; Heart rate less than 60bpm or diastolic blood pressure <50 mmHg during the preoperative visit. |
| Target sample size | 106 |
| Interventions | IV-PCA morphine + Propranolol PO (Experimental): The morning of the surgery a dose of Propranolol 20 mg PO will be administered. After surgery pain control will be performed with IV-PCA morphine; in addition a second dose of Propranolol 20 mg PO will be administered.  Placebo IV-PCA morphine + Placebo PO: ain control after surgery will be performed through IV-PCA morphine. Placebo will be administered with the same schedule of Propranolol in the experimental arm. |
| Outcomes | Primary outcome: Total morphine delivered by IV-PCA [Time Frame: Day II Post-op]  Secondary outcomes: Pressure Pain Threshold by digital pressure algometer [Time Frame: Pre-op visit, Day I Post-op, Day II Post-op, four weeks]; Hyperalgesia test by von Frey hair [Time Frame: Pre-op visit, Day I Post-op, Day II Post-op, four weeks]; Pain measured by the Numerical pain Rating Scale [Time Frame: Pre-op visit, one evaluation during the first 8 Post-op hours, Day I Post-op, Day II Post-op, 4 weeks, 3 months, 6 months]; Somatization, depression and anxiety by SCL-90-R subscales [Time Frame: Pre-op visit]; Sleep quality by PSQI [Time Frame: Pre-op visit, 4 weeks, 3 months, 6 months]; Pain quality [Time Frame: one evaluation during the first 8 Post-op hours, Day I Post-op, Day II Post-op]; Post-operative Chronic Pain [Time Frame: Pre-op visit, Day II Post-op, 4 weeks Post-op, 3 months, 6 months] |
| Starting date | December 2015 |
| Contact information | Principal Investigator: Luda Diatchenko, Professor, Anesthesia Department McGill University |
| Notes | This study has been suspended due to difficulty with recruitment. First received on July 23, 2015. Last update posted on March 22, 2018. <https://clinicaltrials.gov/ct2/show/NCT02511483> |

**NCT02601651**

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| Trial name or title | Effect of Perioperative Intravenous Lidocaine on Opioid Consumption and Pain After Laparoscopic Totally Extraperitoneal Inguinal Hernioplasty |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Male patients with ASA physical status I and II, age 18 to 65 years undergoing laparoscopic totally extraperitoneal repair for unilateral/bilateral inguinal hernia.  Exclusion Criteria: ASA physical status III or more; Inability to comprehend pain assessment score or severe mental impairment; < 40 kg or >100 kg; Severe underlying cardiac rhythm disorder; Renal or hepatic disease; Allergic to local anaesthetics; Epilepsy; Patients on regular analgesics or anti-arrhythmic drugs |
| Target sample size | 64 |
| Interventions | Lidocaine: intravenous (IV) bolus 1.5 mg/kg at induction followed by continuous infusion of 2 mg/kg/hr until the tracheal extubation.  Placebo (Normal saline): intravenous normal saline bolus at induction followed by continuous infusion of normal saline until the tracheal extubation |
| Outcomes | Primary outcome: Total morphine requirement during the first 24 h postoperatively  Secondary outcomes: Pain at rest and with coughing or movement using the NRS scale [Time Frame: 24h]; Time to first perception of pain [Time Frame: 24h]; Incidence of postoperative nausea and vomiting (PONV) [Time Frame: 24h]; Sedation score [Time Frame: 24h]; Time to first voiding [Time Frame: 24h]; Quality of Recovery [Time Frame: 24h]; Patient satisfaction following surgery [Time Frame: 24h]; Other side effects [Time Frame: 24h]; Incidence of Chronic pain [Time Frame: 3 months] |
| Starting date | December 2015 |
| Contact information | Study Director: Asish Subedi, MD, B.P. Koirala Institute of Health Sciences |
| Notes | This study has been completed. First received on November 9, 2015. Last update posted on Sept. 25, 2018.  Actual study completion date: March 2017.  <https://clinicaltrials.gov/ct2/show/NCT02601651> |

**NCT02729805**

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| Trial name or title | Intraoperative Ketamine on Chronic Pain After Mastectomy |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults 18-80 years old, ASA physical status I-III, scheduled for 1) modified radical mastectomy (including axillary lymph node dissection) and 2) mastectomy with sentinel lymph node (without axillary dissection)  Exclusion criteria: Radical mastectomy, wide local excision or lumpectomy; Known allergy to opioids, local anaesthetic drugs, non-steroidal anti-inflammatory drugs (NSAIDS) including COX-2 inhibitors; History of chronic pain; Alcohol or drug abuse; Impaired renal function; Pre-existing neurological or muscular disorders; Psychiatric illness; Impaired or retarded mental state; Not self ambulatory before operation; Difficulties in using patient controlled analgesia (PCA); Pregnancy; Local infection; Patient refusal |
| Target sample size | 135 |
| Interventions | Ketamine 0.5mg/kg: bolus injection of intravenous ketamine at a dose of 0.5mg/kg during anaesthetic induction before skin incision followed by 0.25mg/kg/hr intravenous ketamine infusion during the operation.  Ketamine 0.75mg/kg: bolus injection of intravenous ketamine at a dose of 0.75mg/kg during anaesthetic induction before skin incision followed by 0.5mg/kg/hr intravenous ketamine infusion during the operation.  Placebo: A syringe of 50 ml 0.9% normal saline will be prepared as placebo for infusion and a syringe of 10ml 0.9% normal saline for bolus injection. |
| Outcomes | Primary outcome: Severity of chronic pain [Time Frame: At postoperative 3 months]  Secondary outcome: Incidence of neuropathic pain [Time Frame: At postoperative 3 months] |
| Starting date | August 2015 |
| Contact information | Principal Investigator: Stanley SC Wong, MBBS, The University of Hong Kong |
| Notes | The status of this study is active, not recruiting. Last update posted April 19, 2019.  <https://clinicaltrials.gov/ct2/show/NCT02729805> |

**NCT02786329**

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| Trial name or title | Anesthesia and Postoperative Outcome in Colorectal Cancer Patients |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion criteria: Adults (18-80) with colorectal cancer undergoing elective surgery.  Exclusion Criteria: Persistent chronic pain; chronic medication that may interfere with pain; Contraindications for study medications; Significant psychiatric disorders, hepatic disorders, or Convulsive disorders; planned regional analgesia; Corticoid dependent asthma; Autoimmune disorders; Anti-arrhythmic medication |
| Target sample size | 450 |
| Interventions | Arm 1 TIVA-L: TIVA (propofol-fentanyl) with lidocaine infusion.  Arm 2 TIVA-P: TIVA without lidocaine (placebo saline infusion).  Arm 3 Sevo-P.: Sevoflurane without lidocaine (placebo saline infusion).  Arm 4 Sevo-L: Sevoflurane with lidocaine infusion |
| Outcomes | Primary outcomes: Survival [Time Frame: 5 years]; Incidence of recurrences: [Time Frame: 5 years]  Secondary outcomes: Morphine consumption [Time Frame: 0- 24 h]; Severity of postoperative pain [Time Frame: 0- 48 h]; Resumption of bowel function [Time Frame: 0-72 h]; Length of hospital stay [Time Frame: 0-10 days]; Postoperative chronic pain [Time Frame: 1 year] |
| Starting date | June 2016 |
| Contact information | Daniela Ionescu, Prof Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca; +40744771209; dionescuati@yahoo.com; Caius Breazu, Assist Prof; +40743010012; csbreazu@yahoo.com |
| Notes | This study is currently recruiting participants. Last update posted August 8, 2018.  <https://clinicaltrials.gov/ct2/show/NCT02786329> |

**NCT02862769**

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| Trial name or title | Intra-operative Lidocaine Infusion in Preventing CPSP Post VATs |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (18-75) undergoing video assisted thoracoscopic surgery (VATS) for lobectomy  Exclusion Criteria: Chronic pain including fibromyalgia; Patients using opioids; Major depression; Received or going to receive chemotherapy or radiotherapy; Pregnant |
| Target sample size | 80 (Actual enrollment: 120) |
| Interventions | Lidocaine Group: intraoperative lidocaine infusion (Induction bolus dose of 1.5 mg/kg body weight followed by a continous lidocaine infusion  Placebo Group: intraoperative placebo (Induction bolus dose of 1.5 mg/kg body weight of lidocaine followed by a continous saline infusion at the same rate as the lidocaine infusion. |
| Outcomes | Primary outcomes: Chronic Pain post VATs [Time Frame: 3 & 6 months]  Secondary outcomes: Opioid requirement [48 hours]; Acute Post-Operative Pain [48 hours post-op]; Mean Pain Scores and Pain interference [3 and 6 months] |
| Starting date | January 1, 2017 |
| Contact information | Qutaiba Tawfic Hamodi, Western University; 5196466100 ext 61786; qutaiba.Tawfic@lhsc.on.ca |
| Notes | This study is currently recruiting participants. Last update posted October 24, 2018.  <https://clinicaltrials.gov/ct2/show/NCT02862769> |

**NCT02894710**

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| Trial name or title | Intravenous Lidocaine in Carcinologic ENT Surgery: A Trial for Evaluation of Opioid Saving Strategy and Chronic Postsurgical Pain (ELICO) |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults undergoing major carcinological ENT surgery  Patient receiving standardized Patient Controlled Analgesia (PCA)  Exclusion Criteria: Hypersensitivity to local anesthetics of the amide group; Acute porphyria; Atrioventricular conduction disorders; Epilepsy not controlled by treatment; Hepatocellular insufficiency (PT<50%) or cirrhosis; Systolic heart failure (LVEF <50%); Major inflation State; Hypersensitivity to any component of Glucose 5%; Treatment with beta-blockers or antiarrhythmic of Vaughan Williams classification; BMI > 30kg/m2; Patient already treated for chronic pain with level 3 analgesic or for neuropathic pain; Pregnant or lactating women |
| Target sample size | 128 (Actual enrollment: 143) |
| Interventions | Lidocaine Group: intravenous bolus injection of 1,5 mg/kg lidocaine (0,075mL/kg of Lidocaine 20mg/mL) followed by a continuous lidocaine infusion of 2 mg/kg/hr during surgery (0,1mL/kg/hr of Lidocaine 20mg/mL) and 1 mg/kg/hr in recovery room (0,05mL/kg/hr of Lidocaine 20mg/mL).  Placebo Group: intravenous bolus injection of 0,075mL/kg of placebo (Glucose 5%) by a continuous lidocaine infusion of 0,1mL/kg/hr of placebo (Glucose 5%) during surgery and 0,05mL/kg/hr of placebo (Glucose 5%) in recovery room. |
| Outcomes | Primary outcomes: Total morphine requirement during the first 48 postoperative hours  Secondary outcomes: Remifentanil peroperative consumption [At the end of surgery]; Total morphine requirement [24 postoperative hours]; Chronic post-surgical pain [3 to 6 months after surgery]; Incidence of side effects that can be attributed to lidocaine infusion [3 to 6 months after surgery] |
| Starting date | December 2016 |
| Contact information | Grégoire Wallon: Gregoire.WALLON@lyon.unicancer.fr |
| Notes | This study is currently recruiting participants. Last update posted December 20, 2018.  <https://clinicaltrials.gov/ct2/show/NCT02894710> |

**NCT02925858**

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| Trial name or title | Effect of Ketamine on Analgesia Post-Cardiac Surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Patients 18 years of age or older coming for coronary artery bypass surgery with a left ventricular ejection fraction over 50% and able to consent prior to surgery  Exclusion Criteria: Minimally invasive cardiac surgery; Preoperative opioid use; Preoperative hepatic or renal dysfunction |
| Target sample size | 80 |
| Interventions | Ketamine Group: Intraoperative infusion of ketamine  Placebo Group: saline infusion |
| Outcomes | Primary outcome: Quantity of opioids used in the first 48 hours postoperatively  Secondary outcomes: Quantity of opioids used [First 6, 12, 24 hours postop]; Brief pain inventory [Postop days 0, 1, 2]; PONV [48 hours postop]; Intensive care unit length of stay [1 day - 2 weeks]; Hospital length of stay [5 days - 2 weeks]; Time to extubation [4 hours - 2 weeks]; Medication side effects [48 hours postop]; Delirium [1 week postop]; Chronic Postoperative Pain [3 and 6 months postop]; Time to mobilization [48 hours postop]; Time to ambulation [1 week postop]; |
| Starting date | August 28, 2017 |
| Contact information | Matthew J Cameron, MDCM; 514-340-8222 ext 25701; [matthew.cameron@mcgill.ca](mailto:matthew.cameron@mcgill.ca) |
| Notes | This study is completed. First received October 4, 2016. Last update posted September 6, 2019.  <https://clinicaltrials.gov/ct2/show/NCT02925858> |

**NCT03063931**

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| Trial name or title | Preventive effect of oral magnesium in postmastectomy pain: protocol for a randomised, double-blind, controlled clinical trial |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (≥ 18), with breast cancer scheduled for total mastectomy. |
| Target sample size | 100 |
| Interventions | Magnesium: administered for 6 weeks starting two weeks before the surgery.  Placebo: lactose. |
| Outcomes | Primary outcome: Measure of average pain intensity by a numerical rating scale assessed 5 days before the visit at 1 month post-mastectomy in magnesium and placebo groups.  Secondary outcomes: Pain assessment by the Neuropathic pain questionnaire [Time frame: Month 1 (M1) and Month 3 (M3)]; Evaluation of analgesic consumption [at M3]; Cognitive assessment by Trail Making Test A and B [M1, M3]: Quality of life assessment by EORTC QLQ-C30 [M1, M3]; Quality of life assessment by Pittsburg Sleep Quality Index (PSQI) [M1, M3]; Anxiety and Depression assessment by DASS scale [M1, M3]; Plasma and erythrocyte assays of magnesium [inclusion visit, M1, M3]; Creatinine dosage [at inclusion visit]; Urine assays of magnesium [M1, M3] |
| Starting date | March 2017 |
| Contact information | Professor Gisèle Pickering, MD, PhD, DPharm, Clinical Pharmacology Department, CPC/CIC Inserm 1405, University Hospital CHU, F‐63001 Clermont‐Ferrand, France, [gisele.pickering@uca.fr](mailto:gisele.pickering@uca.fr) |
| Notes | The recruitment status of this study is unknown because the information has not been verified recently. Verified February 2017 by University Hospital, Clermont-Ferrand. Recruitment status was: Not yet recruiting. <https://clinicaltrials.gov/ct2/show/record/NCT03063931> |

**NCT03090776**

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| Trial name or title | Prevention of Post Mastectomy With Intraoperative Ketamine |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: females (18-85) scheduled for total or partial mastectomy |
| Target sample size | 200 |
| Interventions | Ketamine: low dose bolus and infusion ketamine, administered under general anesthesia  Placebo: bolus and infusion saline, administered under general anesthesia |
| Outcomes | Primary outcome: postmastectomy pain [Time Frame: preoperative-2 years post] assessed via breast pain questionnaire, including severity, frequency, related symptoms, and functional impairment |
| Starting date | July 2017 |
| Contact information | Kristin Schreiber, MD/PhD; 612-205-0186, [klschreiber@partners.org](mailto:klschreiber@partners.org) |
| Notes | This study is currently recruiting participants. Last update posted August 8, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03090776> |

**NCT03105765**

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| Trial name or title | Acute and Chronic Pain, Especially Neuropathic Pain, After Thoracotomy and Continuous Application of Ketamine. |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults, ASA Status I-III, scheduled for posterolateral thoracotomy for lung parenchyma resection  Exclusion Criteria: history of chronic pain or neuropathic pain; pregnancy or breastfeeding; participation in another trial; hypersensitivity for ketamine; medication influence neuropathic pain; history of neurological or behavioral illness, alcohol abuse, chemotherapy or radiation; opioid medication |
| Target sample size | 200 |
| Interventions | Ketamine Group: General anaesthesia with total intravenous anaesthesia containing remifentanil (0,02-0,04 mg/kg ideal Body weight), propofol (4-6 mg/kg ideal Body weight) and atracurium.  Ketamine 0,2 mg/kg ideal Body weight per hour for 24 hours.  Placebo Group: General anaesthesia with total intravenous anaesthesia containing remifentanil (0,02-0,04 mg/kg ideal Body weight), propofol (4-6 mg/kg ideal Body weight) and atracurium. Placebo (normal Saline) for 24 hours. |
| Outcomes | Primary outcomes: Change in perioperative opioid consumption [7 days postop]; Change in acute pain [7 days postop]; Acute neuropathic pain [7 days postop]  Secondary outcomes: Change in chronic Pain [1 and 3 month postop]; Chronic Neuropathic pain [1 month postop]; Chronic Neuropathic Pain [3 month postop]; Recovery time [after stopping anesthesia]; |
| Starting date | January 2011 |
| Contact information | Dr. Horst Schmidt Klinik GmbH |
| Notes | This study has been completed. First received on April 3, 2017. Last update posted on April 10, 2017.  Actual study completion date: August 2016.  <https://clinicaltrials.gov/ct2/show/record/NCT03105765> |

**NCT03158376**

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| Trial name or title | Preoperative Gabapentin for Chronic Pain After Thoracotomy (GABATHOMIE) |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (age > 18 years) scheduled for elective lung resection via thoracotomy  Exclusion Criteria: extended pleurectomy and chest wall resection; previous ipsilateral thoracotomy; previous ipsilateral radiotherapy; thoracotomy for pyothorax; chest injury; palliative surgery; contraindicated placement of a thoracic epidural catheter; allergy to medications on protocol; pre-existing pain syndrome; current treatment with morphine, gabapentin, pregabalin, anticonvulsivants or tricyclic antidepressants; a history of past or current drug addiction; severe hepatic, renal or cardiovascular disorders; severe psychiatric disorders; pregnant or lactating woman |
| Target sample size | 200 (Actual enrollment: 238) |
| Interventions | Gabapentin group: the day before surgery gabapentin 400 mg orally, preoperatively (2 hours before surgery) 3 capsules each containing 400 mg gabapentin (total gabapentin dose 1200 mg) and intravenous infusion of 50 ml of normal saline solution, postoperative day 1 to 10 400 mg x 3 (gabapentin 1200 mg daily)  Placebo Group: The day before surgery 1 placebo capsule orally, preoperatively (2 hours before surgery) 3 placebo capsules and, intravenous infusion of 75 mg hydroxyzine, postoperative day 1 to 10 1 placebo capsule x 3 |
| Outcomes | Primary outcome: Persistent chronic post-thoracotomy pain [3 months after surgery]  Secondary outcomes: Acute postoperative pain intensity [10 postoperative days]; Rescue analgesics requirement [3 months post-op]; Volume of epidural infusion [5 days post-op]; Incidence of neuropathic pain [post-op day 2, day 6, 3 months]; Rescue analgesics for neuropathic pain [3 months post-op]; Assessment of hyperalgesia [3 months post-op]; Heath related quality of life [3 months post-op]; Assessment of sedation in the operating room [baseline]; |
| Starting date | September 2015 |
| Contact information | Jacques Desbordes, MD, Lille University Hospital; jacques.desbordes@chru-lille.fr |
| Notes | This study is currently recruiting participants. Last update posted June 26, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03158376> |

**NCT03275207**

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| Trial name or title | Dexmedetomidine for Prevention of Chronic Postoperative Pain |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (18-65) scheduled for breast or thoracic surgery. |
| Target sample size | 120 |
| Interventions | Dexmedetomidine: dexmedetomidine, 0.5ug/kg/h by intravenous infusion, intraoperative  Placebo: an equal volume of saline |
| Outcomes | Primary outcome: Self-reported pain intensity (NRS 0-10) in rest and activity will be recorded at day 1 before surgery, month 3, month 6, month 12 after surgery.  Secondary outcomes: Anxiety VAS 0-10, depression, and sleep disturbance [Time Frame: 12 months] |
| Starting date | January 2018 |
| Contact information | Principle Investigator: Yang Jian-jun, PhD, Zhongda Hospital |
| Notes | The recruitment status of this study is unknown because the information has not been verified recently. Verified December 2017 by Jian-jun Yang, Zhongda Hospital. Recruitment status was: Not yet recruiting.  <https://clinicaltrials.gov/ct2/show/record/NCT03275207> |

**NCT03280017**

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| Trial name or title | Ketamine With Multilevel Paravertebral Block for Post Video-assisted Thoracic Surgery Pain |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (18-70), ASA physical status 1-3, scheduled for elective video-assisted thoracic surgery, able to operate a patient-controlled analgesia device (PCA)  Exclusion Criteria: History of morphine allergy; History of bupivacaine allergy; Contraindication for ketamine infusion; Contraindication for thoracic paravertebral block; Anticipated postoperative positive pressure ventilation; BMI > 35; Any known psychiatric disorder |
| Target sample size | 32 |
| Interventions | Ketamine Group: intravenous ketamine infusion starting after the induction of anesthesia until the end of the surgery at the beginning of skin closure.  Placebo Group: intravenous normal saline solution infusion starting after the induction of anesthesia until the end of the surgery at the beginning of skin closure. |
| Outcomes | Primary outcome: Postoperative morphine consumption [24 hours post-op]  Secondary outcomes: Time to first analgesia [24 hours post-op]; Peak flow rates [1 and 2 days]; Chronic post-surgical pain [1 and 3 months] |
| Starting date | September 25, 2017 |
| Contact information | Sirilak Suksompong, MD; +66891534806; ssuksompong5@gmail.com Panop Limratana, MD; +66879479898; panop89@gmail.com |
| Notes | This study is currently recruiting participants. Last update posted October 5, 2018.  <https://clinicaltrials.gov/ct2/show/record/NCT03280017> |

**NCT03391427**

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| Trial name or title | Ketamine, Lidocaine and Combination for Postoperative Analgesia in Open Liver Resection |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (18-80), ASA physical status 2-4, scheduled for elective major liver resection  Exclusion Criteria: ICU admission after surgery; tracheal extubation not planned after surgery; language barrier; mental impairment; severe coagulopathy; chronic pain or opioid dependance or both; alcohol/substance abuse; allergy to the study drugs; refusal for spinal; infection at site of spinal |
| Target sample size | 124 |
| Interventions | Lidocaine Group: lidocaine infusion perioperatively  Ketamine Group: ketamine infusion perioperatively  Lidocaine+ketamine Group: combination of lidocaine and ketamine infusion, perioperatively  Placebo Group: saline infusion as placebo perioperatively |
| Outcomes | Primary outcome: Opioid consumption [24 hr]  Secondary outcomes: Opioid consumption [48 hrs, 72 hrs]; Opioid related side effects [72 hrs]; Chronic pain [6 weeks, 12 weeks]; Patient satisfaction [72 hrs] |
| Starting date | March 1, 2011 |
| Contact information | Principal Investigator: Achal Dhir, Lawson Health Research Institute |
| Notes | This study has been completed. First received on December 10, 2017. Last update posted on May 29, 2019.  Actual study completion date: December 30, 2017.  <https://clinicaltrials.gov/ct2/show/record/NCT03391427> |

**NCT03419949**

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| Trial name or title | Comparison of Oral Lamotrigine and Oral Pregabalin for Control of Acute and Chronic Pain |
| Methods | Randomized, placebo-controlled, clinical trial |
| Participants | Inclusion: Female patients with ASA I-II, aged 18-60 years, have BMI < 30 km\ m2 and scheduled for modified radical mastectomy with axillary dissection for management of breast cancer |
| Target sample size | 90 |
| Interventions | Group I: patients will receive oral lamotrigine 100 mg 1 hour before surgery with a sip of water.  Group II: patients will receive oral pregabalin 150 mg 1 hour before surgery with a sip of water.  Group III: patients will receive oral placebo 1 hour before surgery with a sip of water. |
| Outcomes | Primary outcome: total amount of rescue morphine received by patients for 24h postoperatively.  Secondary outcomes: level of acute postoperative pain by NRS, the time to first request of rescue analgesia, development of chronic postmastectomy pain after 3 and 6 months postoperatively. |
| Starting date | Not reported. First Posted Date: February 2, 2018 |
| Contact information | Salma Komy, Assiut University, [lolokoke@yahoo.com](mailto:lolokoke@yahoo.com) |
| Notes | The status of this study is “Expanded Access Status: Available.” Last update posted February 6, 2018.  <https://clinicaltrials.gov/ct2/show/record/NCT03419949> |

**NCT03480061**

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| Trial name or title | Dexmedetomidine to Reduce the Incidence of POCD After Open Cardiac Surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (≥60) scheduled for CABG (including off-pump) or valve replacement (+/- CABG) via sternotomy/thoracotomy, with initial recovery in the Cardiovascular Intensive Care Unit (CVICU). |
| Target sample size | 90 |
| Interventions | Dexmedetomidine Hydrochloride Group: Dexmedetomidine will be initiated prior to transfer to the CVICU with loading dose of 1 ug kg-1 over approximately 20 minutes. This will be followed by an infusion at 0.1-1.0 ug kg-1h-1 in CVICU for up to 24 hours from the time DEX infusion started or until the patient is ready for discharge from the CVICU (whichever is earlier).  Standard of Care Group: Standard sedation protocols will be followed at the discretion of the attending physician. |
| Outcomes | Primary outcome: Rate of recruitment [Time Frame: 12 Months]. Ability to recruit 15% a full trial sample size (90 participants).  Secondary outcome: Completion of follow-up assessments [Time Frame: 3 months]. Ability to achieve 90% follow-up of administering cognitive assessment 3 months after surgery. Post-operative outcomes include POCD (3/6/12 months), depression (3/6/12 months), mild cognitive impairment (MCI) at 3/6/12 months (defined as 1-2 standard deviations below age matched controls), persistent surgical site pain at sternotomy/thoracotomy/graft harvest site (Brief Pain Inventory, 3/6/12 months), recovery (3,6, 12 months). |
| Starting date | August 2018 |
| Contact information | Stephen Choi, MD, MSc, FRCPC, 416-480-6100 ext 1711, [stephen.choi@sunnybrook.ca](mailto:stephen.choi@sunnybrook.ca)  Lilia Kaustov, PhD, 416-480-6100 ext 89607, [lilia.kaustov@sunnybrook.ca](mailto:lilia.kaustov@sunnybrook.ca) |
| Notes | This study is currently recruiting participants. Last update posted April 10, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03480061> |

**NCT03527576**

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| Trial name or title | Block Duration After Spinal Block and iv Dexamethasone |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (18 and older), ASA status I-III, scheduled for an osteosynthesis surgery of the lower limb  Exclusion Criteria: Polytrauma patient; Pregnancy; Contraindication to spinal anesthesia; Contraindication to dexamethasone administration; Patient with chronic pain |
| Target sample size | 50 |
| Interventions | Dexamethasone Group: Intravenous injection of 0.15 mg/kg of dexamethasone before the surgery.  Placebo Group: Intravenous injection of NaCl 0,9% before the surgery. |
| Outcomes | Primary outcome: Duration of sensory block [Postop day 0]  Secondary outcomes: Highest dermatoma reached [Postop day 0]; Onset time between injection and highest dermatoma [Postop day 0]; Total duration of the sensory block [Postop day 0]; Total duration of the motor block [Postop day 0]; Time to the first analgesic request [Postop day 0]; Cumulative consumption of morphine [Postop days 0, 1, 2]; Pain score [Postop days 0, 1, 2]; Rate of PONV [Postop days 0, 1, 2]; Rate of pruritus [Postop days 0, 1, 2]; Rate of urinary retention [Postop days 1, 2]; Satisfaction level [Postop day 2]; Length of stay [up to 14 days]; Persistent pain [3 and 6 postop months]; Pain score if persistent pain [3 and 6 postop months] |
| Starting date | May 1, 2018 |
| Contact information | Eric Albrecht, PD Dr; +41 79 556 63 41; eric.albrecht@chuv.ch  Jonathan Frauenknecht; +41 78 960 51 86; jonfrauen@bluewin.ch |
| Notes | This study is currently recruiting participants. Last update posted July 23, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03527576> |

**NCT03534895**

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| Trial name or title | Does the Preoperative Midazolam Dose Affect Postoperative Pain? |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: adult patients submitted to open inguinal hernia repair, varicose vein stripping, knee arthroscopy or hallux valgus surgery in Portuguese ambulatory surgery units |
| Target sample size | 168 |
| Interventions | Group 1: midazolam 0.02mg/Kg in 5mL normal saline, intravenous, single-administration, as pre-medication  Group 2: midazolam 0.06mg/Kg in 5mL normal saline, intravenous, single-administration, as pre-medication  Placebo: 5mL normal saline intravenous, single-administration, as pre-medication |
| Outcomes | Primary outcome: Postoperative pain day 1 after surgery.  Secondary outcomes: Postoperative pain [Day 7, Month 3 after surgery], Pain interference in daily life [Day 1, Day 7, Month 3 after surgery], Analgesic consumption [Day 1 and Day 7 after surgery], Total analgesic drugs taken in a time period (first day after surgery), Patient satisfaction [Day 7, Month 3 after surgery], Adverse events [Day 7 after surgery], Global surgery recovery index [Month 3 after surgery]. |
| Starting date | May 2019 |
| Contact information | Caroline Dahlem, MD +351968061851, [caroline.dahlem@gmail.com](mailto:caroline.dahlem@gmail.com) |
| Notes | This study is not yet open for participant recruitment. Last update posted May 23, 2018.  <https://clinicaltrials.gov/ct2/show/record/NCT03534895> |

**NCT03666299**

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| Trial name or title | Lidocaine Infusion for Postthoracotomy Pain Syndrome |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (18-70), scheduled to undergo a muscle-sparing lateral minithoracotomy for different thoracic diseases  Exclusion Criteria: ASA status III or above; Body weight＜35kg; Liver cirrhosis; A history of previous thoracotomy; Pregnancy; Severe arrhythmia; Congestive heart failure; Opioid or steroid use 6 months before surgery; Allergy to lidocaine; Chronic pain syndrome; Emergency surgery |
| Target sample size | 72 |
| Interventions | Lidocaine Group: Infusion of 2% lidocaine hydrochloride at 4 mL/h, started after tracheal intubation and discontinued until 24 h after surgery.  Placebo Group: Infusion of normal saline at 4 mL/h, started after tracheal intubation and discontinued until 24 h after surgery. |
| Outcomes | Primary outcome: Occurrence of chronic pain [3 months after surgery]  Secondary outcomes: Postoperative acute pain [postop days 1 and 2]; Sedation [postop days 1 and 2]; PONV [postop days 1 and 2]; Fatigue [postop days 1 and 2]; Occurrence of chronic pain at 6-month [6 months after surgery] |
| Starting date | November 6, 2018 |
| Contact information | Xiangcai Ruan, PhD; +8620-81048306; [xc\_ruan@hotmail.com](mailto:xc_ruan@hotmail.com)  Danyang Pan, MD; +86-13246886285; [Pandy0505@163.com](mailto:Pandy0505@163.com) |
| Notes | This study is currently recruiting participants. Last update posted November 7, 2018.  <https://clinicaltrials.gov/ct2/show/record/NCT03666299> |

**NCT03673163**

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| Trial name or title | Lidocaine Infusion for Pain After Herniotomy |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (18-70), scheduled to undergo unilateral inguino herniotomy  Exclusion Criteria: ASA status III or above; Body weight＜35kg; Liver cirrhosis; A history of previous herniotomy; Pregnancy; Severe arrhythmia; Congestive heart failure; Opioid or steroid use 6 months before surgery; Allergy to lidocaine; Chronic pain syndrome; Emergency surgery |
| Target sample size | 180 |
| Interventions | Lidocaine Group: Infusion of 2% lidocaine hydrochloride at 4 mL/h,prior to surgery and discontinued until 24 h after surgery.  Placebo Group: Infusion of normal saline at 4 mL/h, prior to surgery and discontinued until 24 h after surgery. |
| Outcomes | Primary outcome: Occurrence of chronic pain [3 months after surgery]  Secondary outcomes: Postoperative acute pain [Up to 48 hours postop]; Sedation [Up to 48 hours postop]; PONV [Up to 48 hours postop]; Fatigue [Up to 48 hours postop]; Chronic pain at 6-month and 12-month after surgery |
| Starting date | November 6, 2018 |
| Contact information | Xiangcai Ruan, PhD; +8620-81048306; [xc\_ruan@hotmail.com](mailto:xc_ruan@hotmail.com)  Danyang Pan, MD; +86-13246886285; [Pandy0505@163.com](mailto:Pandy0505@163.com) |
| Notes | This study is currently recruiting participants. Last update posted November 7, 2018.  <https://clinicaltrials.gov/ct2/show/record/NCT03673163> |

**NCT03676114**

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| --- | --- |
| Trial name or title | Effect of Perioperative Low Dose Ketamine on Postoperative Recovery in Patients Undergoing Breast Cancer Surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Female adults (20-65), ASA status I-II, undergoing elective breast cancer surgery under general anesthesia  Exclusion Criteria: Unstable hypertension, history of heart disease; Hepatic or renal dysfunction; Undergoing chemotherapy before surgery; History of chronic pain or chronic use of analgesic; History of ketamine allergy |
| Target sample size | 100 |
| Interventions | Ketamine Group: 0.5mg/kg intravenous ketamine injection before incision followed by 0.25mg/kg/hr intravenous ketamine infusion during the operation  Placebo Group: Same volume of normal saline will be administrated |
| Outcomes | Primary outcome: QoR40 score [first day after surgery ]  Secondary outcomes: ICFS scores [Postop 3, 7, and 30 days ]; HADS scores [Postop 2 days and 3months ]; Chronic Pain [3 months after surgery ]; NRS pain scores [4, 24, and 48 hours after surgery]; Postoperative complications [Postoperative 1, 2, and 3 days ] |
| Starting date | September 20, 2018 |
| Contact information | Junli Cao; +86 15162160809; [caojl0310@yahoo.com.cn](mailto:caojl0310@yahoo.com.cn)  Yuan Han; +86 13852470693; [hanyuan-trial@163.com](mailto:hanyuan-trial@163.com) |
| Notes | This study is currently recruiting participants. Last update posted September 20, 2018.  <https://clinicaltrials.gov/ct2/show/record/NCT03676114> |

**NCT03677817**

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| Trial name or title | Perioperative Lidocaine Administration in Thoracoscopic Surgery for Improved Postoperative Pain Control |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion Criteria: Adults (≥ 18 years), ASA status I to III, undergoing video-assisted thoracoscopic procedures under general anaesthesia.  Exclusion Criteria: Contraindications to class of drugs under study or to self-administration of opioids; Pregnant or breast feeding; Steroid therapy; Chronic pain therapy; Congestive heart failure; Liver insufficiency; Known or suspected non-compliance, drug or alcohol abuse. |
| Target sample size | 56 |
| Interventions | Lidocaine Group: perioperative IV administration regimen of lidocaine will be as follows: 1.5 mg/kg IV induction bolus dose (before intubation and at least 30 minutes before incision) followed by continuous infusion of 3.mg/kg/h, until 2 hours after skin closure  Placebo Group: perioperative IV administration regimen of placebo solution (NaCl 0,9%) will be as follows: induction bolus (before intubation and at least 30 minutes before incision) followed by continuous infusion of placebo solution (NaCl 0,9%) until 2 hours after skin closure |
| Outcomes | Primary outcomes: Change in total morphine consumption and change in pain intensity [within the first 24 hours postop]  Secondary outcomes: Duration of hospital stay; Time to first defecation; PONV; Change in chronic pain [2 weeks, 3 and 6 months post op] |
| Starting date | March 2019 |
| Contact information | Aljaz Hojski, Dr. med; +41 61 55 65282; aljaz.hojski@usb.ch  Didier Lardinois, Prof. Dr. MD; +41 61 328 7799; didier.lardinois@usb.ch |
| Notes | This study is currently recruiting participants. Last update posted October 23, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03677817> |

**NCT03714867**

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| Trial name or title | Pre-Operative Pregabalin for Post-Operative Pain in Head and Neck Cancer Surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: English-speaking patients who are greater than eighteen years of age with a known diagnosis of head and neck cancer and are planned to undergo surgery with bilateral neck dissections will be eligible for this study. |
| Target sample size | 111 |
| Interventions | Pregabalin: patients will be administered a single enteral dose of concealed over-encapsulated Pregabalin 150mg in the pre-operative holding area.  Placebo: patients will be administered a single enteral dose of concealed over-encapsulated placebo capsules in the pre-operative holding area. |
| Outcomes | Primary outcome: Brief Pain Inventory [Time Frame: 2 years].  Secondary outcomes: Defense and Veterans Pain Rating Scale [Time Frame: 2 years], University of Washington Quality of Life Scale Version 4 (UW-QOL-4) [Time Frame: 2 years], EuroQol 5D-5L [Time Frame: 2 years], Inpatient morphine equivalents [Time Frame: 1-7 days or longer depending on LOS] |
| Starting date | December 2018 |
| Contact information | Principal Investigator: James K Byrd, MD, Augusta University |
| Notes | This study is currently recruiting participants. Last update posted January 7, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03714867> |

**NCT03825965**

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| Trial name or title | Cannabinoids vs. Placebo on Persistent Post-surgical Pain Following TKA: a Pilot RCT |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (≥18) undergoing TKA. |
| Target sample size | 40 |
| Interventions | Cannabidiol (CBD): Oral medicinal cannabis (125 mg cannabidiol daily suspended in oil)  Placebo: Visually identical placebo (medium chain triglyceride oil) |
| Outcomes | Primary outcome: Proportion of patients experiencing moderate to severe PPSP (average of pain over last week of ≥4 out of 10 on a numeric rating scale [NRS]) [Time Frame: 6 months]  Secondary outcomes: Opioid use [Time Frame: 6 months], Peri-operative pain intensity [Time Frame: 24-48 hours, 2-weeks, 6-weeks, 3-months and 6-months], Pain interference [Time Frame: 24-48 hours, 2-weeks, 6-weeks, 3-months and 6-months], Physical function (PCS) score of the SF-12 [Time Frame: 6 months], Mental function (MCS) score of the SF-12 [Time Frame: 6 months], Return to 80% of pre-injury function (work, leisure, home activities) [ Time Frame: 6 months], Insomnia [Time Frame: 6 months], Anxiety and depression [Time Frame: 6 months], Safety - Adverse events [Time Frame: 6 months] |
| Starting date | April 2019 |
| Contact information | Contact: Anthony Adili, MD, P.Eng (905) 522-1155 ext 36062, [adilia@mcmaster.ca](mailto:adilia@mcmaster.ca)  Contact: Kim Madden, PhD (289) 237-7380, [maddenk@mcmaster.ca](mailto:maddenk@mcmaster.ca) |
| Notes | This study is not yet open for participant recruitment. Last update posted March 8, 2019.  <https://clinicaltrials.gov/ct2/show/record/NCT03825965> |

**NCT03880916**

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| Trial name or title | Effects of Duloxetine on Postoperative Wound Complication of Total Knee Arthroplasty (TKA) in Central Sensitization Patients |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: Patients (>18) with central sensitization inventory (CSI)> 40 scheduled for total knee arthroplasty |
| Target sample size | 80 |
| Interventions | Duloxetine: Phase I (preemptive): 2weeks before operation (30mg for 2weeks); Phase II (maintenance): 6weeks after operation (30mg for 6 weeks)  Placebo: Phase I (preemptive): 2weeks before operation (Placebo for 2weeks) Phase II (maintenance): 6weeks after operation (Placebo for 6 weeks) |
| Outcomes | Primary outcomes: The rates of wound complication, hormone level [from baseline to 12 weeks].  Secondary outcomes: Pain (VAS) and Range of motion of the knee joint [Timeframe: Change from baseline and 2 days, 1, 2, 6, 12 weeks. |
| Starting date | March 2019 |
| Contact information | Not provided. |
| Notes | This study is not yet open for participant recruitment. Last update posted March 19, 2019.  <Https://clinicaltrials.gov/show/nct03880916> |

**NTR6480**

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| Trial name or title | S-ketamine for acute and chronic headache after brainsurgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (18-65) with drug resistant temporal lobe epilepsy who are scheduled for a temporal lobectomy under general anesthesia. |
| Target sample size | 62 |
| Interventions | Ketamine: prior to skin incision 0.25mg/kg bolus s-ketamine followed by a continuous infusion of 0.1mg/kg/u s-ketamine for 48 hours as add-on medication to acetaminophen and opioids.  Placebo: placebo infusion (NaCl 0.9%) in similar administration and dose as the intervention. |
| Outcomes | Primary outcome: Total postoperative opioid consumption at the 7th postoperative day with interim measurements at 24, 48, 72 and 96 hours.  Secondary study outcomes: Postoperative pain scores (VAS+NRS), patient health-related quality of life, psychological parameters, length of hospital stay and adverse events. |
| Starting date | August 2018 |
| Contact information | J.C.T. Sloekers; Phone: +31-43-3875001; [jiske.sloekers@mumc.nl](mailto:jiske.sloekers@mumc.nl) |
| Notes | This study is currently recruiting participants. Last update posted February 24, 2019.  <https://www.trialregister.nl/trial/6305> |

**RBR-555xm5**

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| Trial name or title | Perioperative use of pregabaline in mastectomies |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: Females (20-65) ASA II and III, without renal and hepatic comorbidities, scheduled for mastectomies. |
| Target sample size | 45 |
| Interventions | Pregabalin: 150 mg orally the night before surgery and continued for 14 days after 12 /12 hours.  Placebo: a capsule of the same size and coloration as pregabalin the previous night and continued for 14 days, twice daily for 14 days. |
| Outcomes | Primary outcome: Reduction of chronic postoperative pain.  Secondary outcome: Reduction of acute postoperative pain |
| Starting date | September 2014 |
| Contact information | Miriam Seligman Menezes, Universidade Federal de Santa Maria, Brazil; +55 55 999717728; [miriamsmenezes@gmail.com](mailto:miriamsmenezes@gmail.com) |
| Notes | Data analysis for the study is completed. Last update posted June 15, 2018.  <http://ensaiosclinicos.gov.br/rg/RBR-555xm5/> |

**RBR-7ncggq**

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| Trial name or title | Evaluation of Pain after Knee Surgery using Pregabalin before and after Surgery |
| Methods | Randomized, double-blind, clinical trial |
| Participants | Inclusion: patients (18-75) diagnosed with chronic knee instability, physical status ASA I and II, without local and systemic inflammatory diseases; isolated lesions of the anterior cruciate ligament (no other knee ligaments), no history of fractures in the knee region, absence of previous surgeries in the knee region. |
| Target sample size | 60 |
| Interventions | Pregabalin: 7 days before and 7 days after surgery.  Placebo: 7 days before and 7 days after surgery. |
| Outcomes | Primary outcome: Efficacy of peri-operative pregabalin during the period of 7 days before and 7 days later in the control of postoperative pain using pain scales from the difference of 2 points in the scale in patients submitted to correction of knee ligament by arthroscopy.  Secondary outcome: To evaluate new methods of minimizing or abolishing postoperative pain in patients submitted to knee arthroscopy, after using pain scales with a difference of two points between the scales. |
| Starting date | February 2017 |
| Contact information | Plinio da Cunha Leal, Hospital São Domingos, Brazil, +5598988522021, [pliniocunhaleal@hotmail.com](mailto:pliniocunhaleal@hotmail.com) |
| Notes | This study is currently recruiting participants. Last update posted May 30, 2018.  <http://www.ensaiosclinicos.gov.br/rg/RBR-7ncggq/> |