# Appendix 3: Data extraction form

Information included on this form should be comprehensive, and may be used in the text of your review, ‘Characteristics of included studies’ table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

* Be consistent in the order and style you use to describe the information for each report.
* Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.

|  |
| --- |
| **Review title or ID** |
| Effectiveness and safety of addition fentanyl and/or morphine to intrathecal bupivacaine for caesarean section |

|  |
| --- |
| **Study ID** *(surname of first author and year first full report of study was published e.g. Smith 2001)* |
|  |

|  |
| --- |
| **Language of abstract:**  **Language of the full paper:** |

## General Information

|  |  |
| --- | --- |
| **Date form completed** *(dd/mm/yyyy)* |  |
| **Name of person extracting data**  *(The consensus reviewer should make sure that he agrees with the data extracted for his paired reviewer)* |  |
| **Report author contact details** |  |
| **Publication type**  *(e.g. full report, abstract)* |  |
| **Study funding sources**  *(including role of funders)* |  |
| **Possible conflicts of interest**  *(for study authors, circle one)* | Stated–exists, Stated–no conflict exists, Not-stated |
| **Notes:** |  |

## Study Eligibility

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study Characteristics** | **Eligibility criteria** | | Yes | No | Unclear | **Location in text**  *(pg & ¶/fig/table)* |
| **Type of study** | Randomised Controlled Trial | |  |  |  |  |
| **Participants** | Adults (>18 yrs) having spinal anesthesia for C- section surgery | |  |  |  |  |
| **Types of intervention** | Bupivacaine used as Hyperbaric or Isobaric with or without opioid adjuvant | |  |  |  |  |
| **Single injection spinal** | Only single shot spinals were included in study (Exclude continuous catheters or CSE) | |  |  |  |  |
| **Opioids** | Fentanyl or Morphine used as adjuvants (Please exclude if other opioids or other adjuvants added to local anesthetic mixture) | |  |  |  |  |
| **LA dose** | Was same dose of LA used in both groups? (Please exclude if different dose (mg) used in two groups) | |  |  |  |  |
| **Sub-groups** | 1. Intrathecal morphine vs placebo 2. Intrathecal fentanyl vs placebo 3. Intrathecal morphine and fentanyl vs morphine only   (exclude if any other comparators) | |  |  |  |  |
|  |  | | Exclude if any above is NO | | |  |
| **INCLUDE** | | **EXCLUDE**  **UNCLEAR**  Please contact me if unclear | | | | |
| **Reason for exclusion** |  | | | | | |
| **Notes:** | | | | | | |
| **If answer to any of the following questions is NO, exclude the study and do not perform full text screening** | | | | | | |

## Population and setting

|  |  |  |
| --- | --- | --- |
|  | **Description**  *Include comparative information for each group (i.e. intervention and controls) if available* | **Location in text**  *(pg & ¶/fig/table)* |
| **Country where study was done**  *(Not country of reporting authors)* |  |  |
| **Trial Centre**  *(Name of hospital where trial conducted)* |  |  |
| **Multicentre study**  *(if multicentre state all centres)* | YesNoUnclear |  |
| **Date of trial**  **(From-to dates)** | From: to: Not stated |  |
| **Urgency**  *(e.g. elective c/s, urgent c/s, category of urgency if given)*  *Please give as much detail as available* |  |  |
| **Duration of Surgery** *(central tendency, circle or delete one and give value* | Mean, Median, Mode |  |
| **Duration of surgery** *(Variance) , circle or delete one and give value* | SD, SE, IQR (Q1-Q3), or Range |  |
| **Notes:** | | |

## Methods: Participants and intervention

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Descriptions as stated in report/paper** | | **Location in text**  *(pg & ¶/fig/table)* |
| **Primary aim or objective or outcome of study** *(if given please note, if not given please say not clear/stated)* |  | |  |
| **Secondary outcome measures** (list all stated) |  | |  |
| **Design**  *How many groups.*  *State all comparator.*  *E.g. group A: 2 ml 0.75% hyperbaric bupivacaine, with 15mcg fentanyl*  *Group B: 2 ml 0.75% hyperbaric bupivacaine, with 0.3 ml saline*  *Group C: ……* |  | |  |
| **Total number of participants in the study**  **(N)** |  | |  |
| **Dose of bupivacaine**  *(e.g. 12 mg each group)* |  | |  |
| **Dose of Fentanyl**  *(e.g. 15 mcg)* |  | |  |
| **Dose or Morphine**  *(e.g. 100 mcg)* |  | |  |
| **Pre-loading, prophylactic vasopressor used**  *(dose and type of fluid or vasopressor)* |  | |  |
| **Type of spinal needle used**, e.g. 24 G sprotte |  | |  |
| **Providers/Personnel**  *(e.g. Trainee/Consultant)* |  | |  |
| **Position spinal performed in each group**  *(supine/lateral/sitting)* |  | |  |
| **Duration kept in position after spinal (minutes)** |  | |  |
| **Final position for surgery**  *(supine/lateral/sitting)* |  | |  |
| **Sedation or iv analgesia received during C/S** *(state drug used and dose)* |  | |  |
| **Sample size calculation done** | Yes/ No/ Unclear | |  |
| **Analysis method** *(please circle or delete)* | Intention to treat (ITT) or Per Protocol Analysis (PPO) or not stated | |  |
| **Method of dealing with exclusions given** *(if yes please note* | YesNoUnclear |  |  |
| **Notes:** | | | |

## Risk of Bias assessment

*See* [*Chapter 8*](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/index.htm#chapter_8/8_assessing_risk_of_bias_in_included_studies.htm) *of the Cochrane Handbook*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Domain** | **Risk of bias** | | | **Support for judgement**  **Mention what was actually done** | **Location in text**  *(pg & ¶/fig/table)* |
|  | Low risk | High risk | Unclear |  |  |
| **Random sequence generation**  *(selection bias)* |  |  |  |  |  |
| **Allocation concealment**  *(selection bias)* |  |  |  |  |  |
| **Blinding of participants and personnel**  *(performance bias)* |  |  |  |  |  |
| **Blinding of outcome assessment**  *(detection bias)* |  |  |  |  |  |
| **Incomplete outcome data**  *(attrition bias)* |  |  |  |  |  |
| **Selective outcome reporting?**  *(reporting bias)* |  |  |  |  |  |
| **Notes:** | | | | | |

## Outcomes*.*

***Primary outcomes***

1. Inadequate pain control requiring conversion to general anesthesia (dichotomous)
2. Inadequate pain control requiring use of supplemental analgesics (dichotomous)

***Secondary outcomes***

1. Incidence of hypotension or bradycardia requiring treatment (with patient as unit of measurement)
2. Incidence of nausea/vomiting requiring treatment (with patient as unit of measurement)
3. Incidence of pruritus requiring treatment (with patient as unit of measurement)
4. Incidence of urinary retention requiring catheterization (with patient as unit of measurement)
5. Onset time: Time to dermatomal block at the 4th thoracic vertebra (T4) level (continuous)
6. Duration of motor (minutes): Time to bromage scale 1 (continuous)
7. Duration of analgesia as defined by time to first rescue analgesia request (continuous)
8. Incidence of respiratory depression

## Results

***Outcome 1: Need for conversion to general anesthesia (Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was conversion decided** (e.g. Patient discomfort, moving legs, checked for sensory block) |  | | | | |  |
| **Results**  **Event = no. of patients how got converted to GA** | **Fentanyl/morphine** | | | **Control group** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
|  |  | | | | |  |
| **Statistical methods used** *(e.g. test used)* |  | | | | |  |
| **Notes:** |  | |  | | |  |
|  | | | | | | |

***Outcome 2: Inadequate pain control requiring use of supplemental analgesics (Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was used** (e.g. Patient discomfort, patient request etc.) |  | | | | |  |
| **Results**  **Event = no. of patients** | **Fentanyl/morphine** | | | **Control group** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
| **What analgesia/sedative was used and reason (e.g. Ketamine, nitrous oxide)** |  | | | | |  |
| **Statistical methods used** *(e.g. test used)* |  | | | | |  |
| **Notes:** |  | |  | | |  |
|  | | | | | | |

***Outcome 3: Incidence of hypotension or bradycardia needing treatment (Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was used** (e.g. 20% drop from baseline etc.) |  | | | | |  |
| **Results**  **Event = no. of patients needing treatment** | **Fentanyl/morphine** | | | **Control group** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
| **What treatment was given (e.g. ephedrine 5-10 mg, atropine 0.3 mg))** |  | | | | |  |
|  |  | | | | |  |
| **Statistical methods used** *(e.g. test used)* |  | | | | |  |
| **Notes:** |  | |  | | |  |
|  | | | | | | |

***Outcome 4: Incidence of nausea/vomiting (Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was used** (e.g. nausea score, one vomiting episode etc.) |  | | | | |  |
| **Results**  **Event = no. of patients** | **Fentanyl/morphine** | | | **Control** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
|  |  | | |  | |  |
| **Statistical methods used** *(e.g. test used))* |  | | | | |  |
| **Notes:** |  | |  | | |  |
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***Outcome 5:* Incidence of pruritus requiring treatment *(Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was used** (e.g. pruritus score, patient request etc.) |  | | | | |  |
| **Results**  **Event = no. of patients** | **Fentanyl/morphine** | | | **Control** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
|  |  | | |  | |  |
| **Statistical methods used** *(e.g. test used))* |  | | | | |  |
| **Notes:** |  | |  | | |  |
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***Outcome 6:* Incidence of urinary retention requiring catheterization *(Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was used** (e.g. unable to pass urine after 6 hours or not stated etc.) |  | | | | |  |
| **Results**  **Event = no. of patients** | **Fentanyl/morphine** | | | **Control** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
|  |  | | |  | |  |
| **Statistical methods used** *(e.g. test used))* |  | | | | |  |
| **Notes:** |  | |  | | |  |
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***Outcome 7: Onset time***, ***Time to dermatomal block at the 4th thoracic vertebra (T4) level (Continuous outcome)***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Description as stated in report/paper** | | | | | | | **Location in text**  *(pg & ¶/fig/table)* | |
| **State any other definition used** | |  | | | | | | |  | |
| **Time-points** *(e.g. completion of spinal injection to T4 by cold testing)* | |  | | | | | | |  | |
| **Results**  **Circle or delete** | **Fentanyl/morphine** | | | | | **Control** | | |  | |
| Mean/median(min) | | SD (or other variance e.g. SEM please state) | No. participants | | Mean | SD (or other variance) | No. participants |  | |
|  | |  |  | |  |  |  |
| **No. missing participants and reasons** | |  | | | |  | | |  | |
| **Statistical methods used and appropriateness of these methods** | |  | | | | | | |  | |
| **Notes:** | |  | | |  | | | |  | |
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***Outcome 8: Time to complete regression of motor block (Bromage 1) (Continuous outcome)***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Description as stated in report/paper** | | | | | | | **Location in text**  *(pg & ¶/fig/table)* | |
| **State any other definition used** | |  | | | | | | |  | |
| **Time-points** *(e.g. completion of spinal injection to achieving bromage scale 1 )* | |  | | | | | | |  | |
| **Results**  **Circle or delete** | **Fentanyl/morphine** | | | | | **Control** | | |  | |
| Mean/median(min) | | SD (or other variance e.g. SEM please state) | No. participants | | Mean | SD (or other variance) | No. participants |  | |
|  | |  |  | |  |  |  |
| **No. missing participants and reasons** | |  | | | |  | | |  | |
| **Statistical methods used and appropriateness of these methods** | |  | | | | | | |  | |
| **Notes:** | |  | | |  | | | |  | |
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***Outcome 9:* Duration of analgesia as defined by time to first rescue analgesia request *(Continuous outcome)***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Description as stated in report/paper** | | | | | | | **Location in text**  *(pg & ¶/fig/table)* | |
| **State any other definition used** | |  | | | | | | |  | |
| **Time-points** *(e.g. completion of spinal, completion of surgery – to request )* | |  | | | | | | |  | |
| **Results**  **Circle or delete** | **Fentanyl/morphine** | | | | | **Control** | | |  | |
| Mean/median(min) | | SD (or other variance e.g. SEM please state) | No. participants | | Mean | SD (or other variance) | No. participants |  | |
|  | |  |  | |  |  |  |
| **No. missing participants and reasons** | |  | | | |  | | |  | |
| **Statistical methods used and appropriateness of these methods** | |  | | | | | | |  | |
| **Notes:** | |  | | |  | | | |  | |
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|  | |  | | | | | | |  | |
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***Outcome 10: Incidence of Respiratory depression (Dichotomous outcome)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| **On what criteria was used** (e.g. respiratory rate less than, SpO2 less than etc.) |  | | | | |  |
| **Results**  **Event = no. of patients** | **Fentanyl/morphine** | | | **Control** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
|  |  | | |  | |  |
| **Statistical methods used** *(e.g. test used))* |  | | | | |  |
| **Notes:** |  | |  | | |  |
|  | | | | | | |

## Conclusions

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| --- |
| **Please list key conclusions or author conclusions. You can copy and paste author conclusion from article** |
|  |

**If there is a lot of missing data contact Dr. Vishal Uppal before extraction of next study**