ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: June 3, 2019

ClinicalTrials.gov ID: NCT03974321

Study Identification

Unique Protocol ID:	20180713
Brief Title:	Intraoperative Hypotension and Perioperative Myocardial Injury
Official Title:	Association Between Intraoperative Hypotension and Perioperative Myocardial Injury: a Nested Case Control Study
Secondary IDs:	

Study Status

Record Verification:	June 2019
Overall Status:	Recruiting
Study Start:	May 1, 2019 [Actual]
Primary Completion:	June 15, 2019 [Anticipated]
Study Completion:	September 30, 2019 [Anticipated]

Sponsor/Collaborators

Sponsor:	Karolinska Institutet
Responsible Party:	Principal Investigator Investigator: Max Bell [mbell] Official Title: MD, PhD, Associate Professor, Senior Lecturer Affiliation: Karolinska Institutet
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 2014/1306-31/3 Board Name: Regionala Etikprövningsnämnden Board Affiliation: Etikprövningsmyndigheten Phone: 0046 10 475 08 00 Email: registrator@etikprovning.se Address: Etikprövningsmyndigheten

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Data Monitoring:

Study Description

Brief Summary: Acute myocardial infarction (MI) is a significant complication following non-cardiac surgery. We sought to evaluate incidence of perioperative MI, its preoperative - and intraoperative - risk factors and outcomes after this complication.

Detailed Description: Background:

In Sweden, over 800 000 patents undergo surgery each year. Worldwide, the number of surgical procedures yearly is over 310 million. Surgical care is en essential part of the advancement in treating disease, associated with increased lift expectancy a d improved quality of life. However as surgical volume continues to grow, the number of patients who suffer postoperative complications will also increase.

Hemodynamic instability in the perioperative period is frequent and there has been a cumulative interest in this area and the relation to organ failure over the recent years. There are several studies showing results of associations between intraoperative hypotensive events and perioperative cardiac, kidney and cerebral injury, as well as increased mortality in high-risk surgical patients.

More specifically the project aims to answer how intraoperative events, with a special focus on hypotension, are related to perioperative myocardial and kidney injury.

We hypothesize that patients, with preoperative risk factors, undergoing major non-cardiac surgery are at increased risk of developing perioperative organ damage in the presence of intraoperative hypotension or other events such as tachycardia, hypoxia and extensive blood loss.

Conditions

Conditions: Myocardial Infarction Postoperative
Myocardial Injury
Intraoperative Complications
Intraoperative Hypotension
Perioperative Complication

Keywords:

Study Design

Study Type: Observational [Patient Registry]

Observational Study Model: Case-Control

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 1200 [Anticipated]

Number of Groups/Cohorts: 1

Target Follow-Up Duration: 1 Years

Groups and Interventions

Outcome Measures

Primary Outcome Measure:

1. Acute Myocardial Infarction
   Acute MI, detected in the postoperative phase in the electronic medical records or in the Swedeheart Registry

   [Time Frame: Within 30 days after the index surgery]

Secondary Outcome Measure:

2. Mortality
   Death, detected in the postoperative phase in the Swedish Cause of Death Register.

   [Time Frame: Witis 30 days after the index surgery and at later predefined time points: 60, 90 180 and 365 days after the index surgery.]

Eligibility

Study Population: Adult patients undergoing non-cardiac surgery between 2007 and 2014 at 3 Swedish University hospitals; Karolinska University hospital, Skåne University Hospital and Norrland University hospital.

Sampling Method: Non-Probability Sample

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Cases

Inclusion Criteria:

- Adults (≥18 years), male and female.
- Undergoing elective or non-elective in-patients non-cardiac surgery at 3 University Hospitals in Sweden: Karolinska University hospital, Skåne University hospital and Norrland University hospital.
- Surgeries performed between 2007 and 2014.
- Acute myocardial infarction criteria fulfilled within 30 days after surgery.

Exclusion Criteria:

- Cardiac surgery
- Obstetric surgery

Controls:

Matched (on age, preoperative risk factors, surgical year- site and procedure) surgical patients without myocardial infarction within 30 days after surgery.

Contacts/Locations

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IPDSharing

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References

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