Effect of remote ischemic preconditioning on postoperative asymptomatic myocardial injury after pancreatic surgery: a randomised controlled trial

Published: 10-01-2017
Last updated: 16-04-2024

To determine the effect of RIPC on MINS in patients after pancreatic sugery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON42957

Source
ToetsingOnline

Brief title
MICOLON II

Condition

- Myocardial disorders

Synonym
asymptomatic cardiac troponin elevation, heart injury after surgery, postoperative myocardial injury

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: RND Anesthesiologie;St. Antonius Ziekenhuis

Intervention

Keyword: Ischemic preconditioning, Myocardial injury, Pancreatic surgery

Outcome measures

Primary outcome

Maximum postoperative concentration of high-sensitive cardiac troponin T.

Secondary outcome

Markers of inflammatory, intestinal and renal injury, postoperative

complicatons during 30 days, length of stay and hospital mortality.

Study description

Background summary

High-risk abdominal surgery is frequently complicated by postoperative complications, such as sepsis, pneumonia or anastomotic dehiscence. Asymptomatic myocardial injury after abdominal surgery (MINS) predicts non-cardiac complications. The etiology of MINS in abdominal surgery patients is unknown.
Remote ischemic preconditioning (RIPC) is a physiologic mechanism that exposes tissues to brief periods of non-lethal ischemia and reperfusion, creating resistence for future serious ischemic insults. RIPC in patients after cardiac or aortic surgery is associated with a protective effect on the heart. The effect of RIPC in abdominal surgery patients is unknown.

Study objective

To determine the effect of RIPC on MINS in patients after pancreatic sugery.

Study design

Randomised controlled parallel group mono-center pilot study.

Intervention

RIPC: 3 periods of 5 minutes of ischemia followed by 5 minutes of reperfusion are created by inflating a blood pressure cuff on the upper extremity after induction of anesthesia and prior to surgery. In the control group a non-inflated blood pressure cuff is placed on the upper extremity for 30 minutes.

Study burden and risks

After routine anesthesia screening at the outpatient anesthesia clinic, patients proceed with standard surgical care. Urine samples and blood samples ar collected during the first 48 hours after surgery using an arterial line (rourine care) and urinary catheter (routine care). RIPC or control intervention is performed after induction of anesthesia and does not influence total duration of surgery. RIPC is a simple manoevre without known risk for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 years or older
Scheduled for pancreaticoduodenectomy

Exclusion criteria

Pregnancy
No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2017
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57818.100.16