The effect of preoperative patient warming on the incidence of perioperative hypothermia in surgical patients

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Is the combination of pre- and intraoperative warming more effective in the prevention of perioperative hypothermia in comparison with intraoperative warming in patients undergoing elective surgery?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34349

Source
ToetsingOnline

Brief title
PREWARM study

Condition

- Other condition

Synonym
Hypothermia, low body temperature

Health condition

Anesthesiologische procedure

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hypothermia, Perioperative period, Prewarming

Outcome measures

Primary outcome

Incidence of perioperative hypothermia

Secondary outcome

Amount of perioperative blood loss

Incidence of wound infection.

Study description

Background summary

Hypothermia, defined as a core temperature below 36°C, is commonly seen in patients undergoing surgery. Intraoperative hypothermia is related to increased incidence of wound infection and blood loss. Prewarming patients prior to surgery may result in maintenance of intraoperative temperature and reduce postoperative complications. We therefore aim to investigate the effects of prewarming patients undergoing elective abdominal surgery on intraoperative temperature control.

Study objective

Is the combination of pre- and intraoperative warming more effective in the prevention of perioperative hypothermia in comparison with intraoperative warming in patients undergoing elective surgery?

Study design

Prospective, randomized clinical trial.

Study burden and risks

One group of patients will be subjected to preoperative warming, which is not part of standard clinical care. Discomfort due to prewarming is expected to be minimal. The study is associated with minimal patient risk.

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

Participation based on informed consent
> 18 years old and < 85 years old
Elective abdominal surgery
Estimated duration of operation > 1 hour

General anesthesia with or without epidural

Exclusion criteria

Pregnancy
Non-elective patients
Combined surgery
Anemia (Hb < 6.0)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	130
Type:	Actual

Medical products/devices used

Generic name:	Warming blanket / Warming mattress
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-07-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL32052.029.10