Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparing the study of the effect of two methods of Peri-operative active warming on abdominal surgery patients’ mean core temperature

Protocol summary

Study aim
Determining the effect of two methods of peri-operative active warming on abdominal surgery patients’ mean core temperature

Design
The number of samples was selected according to the criteria for inclusion and exclusion . After obtaining the informed conscientious consent of the patients to participate in the research using software, they are randomly divided into three groups (2 intervention and 1 control).

Settings and conduct
The randomized clinical trial، in the operating room department of fatemehalzahra hospital of Mehriz

Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidate patients for elective abdominal surgery under general anesthesia Age range 18-75 years Body mass index in the range of 20-30 ASA risk:I-III exclusion criteria: Body temperature bellow 36 centigrade degree Existence of metabolic diseases, Infection or temperature outside the normal range in the three days before surgery (fever) History of known thyroid disease History of drug use Taking corticosteroids or non-steroidal anti-inflammatory drugs Blood transfusion during surgery

Intervention groups
Intervention group 1:This semi- experimental study was performed on 180 candidates for elective abdominal surgery by general anesthesia referring to the operating room fatemaalzahra (Mehriz) Hospital in 1399. 60 patients will are subjected to Peri - operative warming by adjusting the electrical blanket temperature by 40 degrees below the body surface. intervention group 2 warmed infusion and irrigation fluid are used and control group receive routine care.

Main outcome variables
central body temperature

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200904048613N1**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **retrospective**

Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date
2022-03-02, 1400/12/11

Registrant information

Name
Mahboubeh Zareian baghdadabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3252 4918

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mahboubeh.zareian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2021-05-10, 1400/02/20

Actual recruitment start date
2020-04-03, 1399/01/15

Actual recruitment end date
2021-05-10, 1400/02/20

Trial completion date
2021-05-10, 1400/02/20

Scientific title

Comparing the study of the effect of two methods of Peri-operative active warming on abdominal surgery patients' mean core temperature

Public title
Investigating the effect of two methods of peri-operative active warming on abdominal surgery patients' mean core temperature

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Elective patients undergoing abdominal surgery under general anesthesia with a mean age of 18-75

Exclusion criteria:
If the central temperature is bellow 36 and above 37.5 centigrade degree

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **180**
Actual sample size reached: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 180 qualified patients selected. First, using Random allocation software version 1 and block random allocation method, we determined the random sequence for numbers 1 to 180. The samples to each of the two intervention groups (receiving infusion and irrigation fluids and warming patients with electric blankets under their body surface) and the control group were randomly assigned in 3 block for each patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to consider blinding, the intervention are performed by a researcher's assistant and the research are completed by the researcher.the researcher didn't know to which groups patients were assigned and the responsible experts in anesthesia and surgical technicians did not inform the patients' classification in each group.

Placebo
Not used

Assignment
Other

Other design features
doesn't have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yazd University of Medical Sciences

Street address
Faculty of Nursing and Midwifery school, Bouali Alley, Teamsar Fallahi st, Safaee, Yazd, Iran

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Yazd

Province
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Postal code
916877443

Approval date
2020-05-17, 1399/02/28

Ethics committee reference number
ir.ssu.rec.1399.039

Health conditions studied

1

Description of health condition studied
patients undergoing elective abdominal surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
central body temperature

Timepoint
pre anesthesia - during anesthesia - after surgery

Method of measurement
Based on degrees C and using the tympanic thermometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1:This semi- experimental study was performed on 180 candidates for elective abdominal surgery by general anesthesia referring to the operating room fatemaalzahra (Mehriz) Hospital in 1399. 60 patients will are subjected to Peri - operative warming by adjusting the electrical blanket temperature by 40 degrees below the body surface

Category
Prevention

2

Description
Intervention group2:warming infusion and irrigation fluid by 38 degree during surgery
Category
Prevention

3

Description
Control group:Receive routine care
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemehalzahra hospital- Mehriz
Full name of responsible person
Mahboubeh Zareian
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Fatema alzahra hospital, Parastar sq, Tir 7th Blv, Mehriz, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Masoud Mirzaei
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Faculty of Nursing and Midwifery School, Bouali Alley, Teamsarfallahi st, Safaee, Yazd
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mahboubeh Zareian
Position
student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only the original outcome data will be available

When the data will become available and for how long
After publishing the article

To whom data/document is available
all the medical researchers

Under which criteria data/document could be used
The usage of data and other documents will be allowed only via the official request from the primary investigator

From where data/document is obtainable
data will be obtainable via the emails of the primary investigator

What processes are involved for a request to access data/document
Access to documents will be possible just by sending email to PI.

Comments