

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 be 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)

Phone

+98 35 3252 4918

Email address

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

City

Yazd

Province

Yazd

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

Street address

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

Street address

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

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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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