Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Assessment The effect of hypothermia prevention program on shivering, core body temperature and recovery time in patients undergoing abdominal surgery

Protocol summary

Study aim

The effect of hypothermia prevention program on shivering, recovery time, central body temperature in patients undergoing abdominal surgery in teaching hospitals of Zahedan University of Medical Sciences in 2019_2020

Design

This study will be performed on 80 patients (male / female) undergoing abdominal surgery who are admitted to n teaching hospitals in2019-2020. They were randomly divided into control and intervention groups.

Settings and conduct

Zahedan University of Medical Sciences Hospitals، In this study, 80undergoing abdominal surgery will be randomly assigned to 40 patients in the control room of routine operating room care. And 40 patients in the intervention group will be heated and disinfected with a heated disinfectant at 32 ° C. Serum infusion will be performed at 37 to 40 ° C. And transferred to the bed after surgery. The patient's central temperature, chills, and hemodynamic characteristics will be measured at seven specified times.And the time spent in recovery is also recorded

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients undergoing elective abdominal surgery, patients receiving general anesthesia, ASA class 1 and 2 patients, surgical incisions above 5 cm, surgery time of at least one hour. Exclusion criteria:Occurrence of any condition affecting the patient's normal anesthesia and surgery, underlying diseases, intraoperative blood transfusion, intravenous fluids greater than 5 liters, significant hypotension during surgery, and non-steroidal analgesic and magnesium sulfate administration

Intervention groups

Group1:Patients according to routine, prep, drep and fluid infusion the same room temperature will receive.

Group 2: Patients Under intervention, receive a hypothermia prevention program during and after surgery.

Main outcome variables

Central body temperature, chills, recovery time, hemodynamic status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200304046691N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-09, 1399/01/21**
Update count: **0**

Registration date

2020-04-09, 1399/01/21

Registrant information

Name

Tayebeh Azarmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-26, 1398/12/07

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment The effect of hypothermia prevention program on shivering, core body temperature and recovery time in patients undergoing abdominal surgery

Public title

The effect of care plan on body temperature and recovery time

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective abdominal surgery including abdominal hernia and open hysterectomy and open cystectomy Patients receiving general anesthesia ASA class 1 and 2 patients Surgical incisions above 5 cm Surgery time of at least one hour and maximum of 2.5 hours

Exclusion criteria:

Occurrence of any condition affecting the patient's normal anesthesia and surgery, such as excessive bleeding and cardiac arrest during surgery Having underlying diseases (thyroid, diabetes, cardiovascular disease and chronic hypertension) Receiving blood and blood products during surgery Intravenous fluids greater than 5 liters during surgery, temperatures above 37.5 ° C or less than 36.5 ° C before surgery Significant hypotension during surgery (20% blood pressure lower than before anesthesia) Endocrine Disorders Corticosteroid intake Non-steroidal analgesic and magnesium sulfate Fever, and addiction Prohibition on controlling body temperature through the tympanic membrane Lack of patient satisfaction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permutation block randomization will be used to allocate participants randomly،So that 80 envelopes are made and each envelope is labeled as A or B. When the first patient meets the inclusion criteria, the first envelope is opened and given the name of the group, if A was in the intervention group and if B was in the control group, the same would be done until the last sample. Comments will be made.

Blinding (investigator's opinion)

Single blinded

Blinding description

The sampling conditions are randomized so that the patient is not aware of the measures to be taken, but since the parameters are measured by the researcher, the blinding researcher does not. The permutation block randomization method will be used

Placebo

Not used

Assignment

Parallel

Other design features

In our study, hypothermia prevention protocol is performed on patients with general anesthesia for abdominal surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research and technology of Mazandaran University of Medical Sciences

Street address

Sari, Imam Square, Jouybar Road, Valiasr Highway, Central Headquarters of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2020-02-26, 1398/12/07

Ethics committee reference number

IR.MAZUMS.REC.1398.1391

Health conditions studied

1

Description of health condition studied

Patients undergoing abdominal surgery Like cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

2

Description of health condition studied

Patients undergoing abdominal surgery Like abdominal hernias

ICD-10 code
K43.2
ICD-10 code description
Incisional hernia without obstruction or gangrene

3

Description of health condition studied
Patients undergoing abdominal surgery Like a hysterectomy
ICD-10 code
N99.3
ICD-10 code description
Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description
Central body temperature
Timepoint
Before Intervention - During Intervention - After Intervention
Method of measurement
Based on the temperature and using a tympan thermometer

2

Description
shiver
Timepoint
During the intervention - after the intervention
Method of measurement
Will be reviewed according to the Crossley classification. Grade 1 = no shiver, grade 2 = slight shivering (straightening of hair, peripheral cyanosis without visible shake), grade 3 = moderate shivering (visible muscle shake in a group of muscles), grade 4 = severe shivering (muscle shake in All body muscles)

3

Description
Recovery time
Timepoint
after surgery
Method of measurement
timer

Secondary outcomes

1

Description
blood pressure
Timepoint
Before intervention - During intervention - After intervention
Method of measurement
Systolic and diastolic blood pressure monitored using a millimeter of mercury

2

Description
Number of pulses
Timepoint
Before intervention - During intervention - After intervention
Method of measurement
Using the monitor on a per-minute basis

3

Description
Breath rate
Timepoint
Before intervention - During intervention - After intervention
Method of measurement
Using the monitor on a per-minute basis

4

Description
Percentage of arterial blood oxygen saturation
Timepoint
Before intervention - During intervention - After intervention
Method of measurement
Using a monitor based on percentages

Intervention groups

1

Description
Intervention group: This clinical trial study will be performed on 80 candidates undergoing abdominal surgery by general anesthesia referring to the operating room of teaching hospitals of Zahedan University of Medical Sciences. Given the random allocation, 40 patients in the intervention group, in this group, after being admitted to the operating room on the surgical bed, received anesthesia induction drugs according to the standard protocol (receiving anesthesia would be the same in both groups) and then receiving permission from the team،intervention Under the heading of a hypothermia prevention program, it is performed on patients with entry criteria, which، Anesthetist will scrub and drip using a heated disinfectant up to 32 ° C (by Warmer machine). Infusion of injectable liquids will begin with warm serum of 37 degrees. After surgery, patients are transferred to the recovery bed. This bed and blanket were prepared half an hour before the patient was transferred to recovery by two to three 40-by-60-cm warm water bags pre-heated with standard anesthetic (Fig. 1) so after placement The patient will be warm on the bed Both the bed and the blanket on the patient will be followed by two smaller warm water bags in the axillary and thigh area of the patient.In both groups, data will be collected on the basis of data collection forms, including personal information and information on

surgery and anesthesia, as well as recording of central temperature, blood pressure, pulse and arterial oxygen saturation, chills. And it will be a recovery time. Seven times will be measured: 5 minutes before anesthesia, 5 minutes after induction of anesthesia, 30 minutes after surgery, after surgery,On arrival to recovery, 0.5 hours and 1 hour after transfer. The patient will be monitored for recovery

Category

Prevention

2

Description

Control group: 40 patients in the control group received routine, routine operating room care, including perforation, drip, and infusion of operating room temperature fluid, and will be transferred to recovery beds after surgery. They will be covered with routine blankets.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating Room of Zahedan University of Medical Sciences Teaching Hospitals

Full name of responsible person

Zahra Pishkar Mofrad

Street address

Zahedan, Persian Gulf Boulevard - Imam Ali Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Tayebeh Azarmehr

Position

University Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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University Student
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available