Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of two methods of warming on the physiological indices during and after laparoscopic abdominal surgery at the Alzahra Hospital of Isfahan in 2017

Protocol summary

Summary

Objective: comparison the effect of two methods of warming on the physiological indices during and after laparoscopic abdominal surgery. Study design: stratified random sampling. Study population: patients with laparoscopic cholecystectomy in Al-Zahra hospital. The main inclusion criteria: no underlying disease and cardiovascular disease; no fever; aged between 18 and 65 years; surgery time up to 2 hours. The main exclusion criteria: need for blood transfusions during and after surgery; intra-abdominal infections; get more than 5 liters of intravenous fluids during surgery. Sample size: 96 patients. Intervention or interventions: the patients to a separate procedure will be warm. Intervention time: immediately after induction of anesthesia, extremities of the patient in the 1 group is heated by the forced air system, warming IV fluids are used for the group 2 until 30 minutes after the end of the surgery. The control group received routine care. Variables before induction of anesthesia, immediately after induction of anesthesia and every 15 minutes until 30 minutes after the end of the surgery will be measured. Intensity of shivering in recovery with an anesthesiologist monitoring and verification by means of observation (Grossley and Mahajan) will be examined. The primary outcome or consequences of the study: changes in physiological parameters and reduce shivering.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041533435N1**
Registration date: **2017-05-16, 1396/02/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-16, 1396/02/26

Registrant information

Name
Fereshteh Baradaran Fard
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 7565
Email address
baradaranfard.f@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-03-08, 1395/12/18

Expected recruitment end date

2017-07-09, 1396/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two methods of warming on the physiological indices during and after laparoscopic abdominal surgery at the Alzahra Hospital of Isfahan in 2017

Public title

Comparison the effect of two methods of warming on the physiological indices during and after laparoscopic abdominal surgery at the Alzahra Hospital of Isfahan in 2017

Purpose
Prevention

Inclusion/Exclusion criteria
The inclusion criteria: satisfaction; no underlying disease (hypothyroidism, hyperthyroidism, diabetes and hypertension) and cardiovascular disease; no fever; aged between 18 and 65 years; surgery time up to 2 hours; no received Corticosteroids and non-steroidal anti-pain; lack of infection; ASA = I - II; BMI = 18.5 - 38. The exclusion criteria: the need for open surgery or return the patient to the operating room; and said heat felt by the patient in recovery; need for blood transfusions during and after surgery; intra-abdominal infections; blood loss during surgery more than 1 liter; Sensitivity to anesthetic drugs; get more than 5 liters of intravenous fluids during surgery; temperature more than 37.5 or less than 36.5 prior to surgery; the need for cardiopulmonary resuscitation during surgery; intraoperative hemodynamic changes include a severe drop in blood pressure and pulse; using humid and warm CO2 gas for pneumoperitoneum.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University Of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran

City
Isfahan

Postal code
81746-73465

Approval date
2017-03-08, 1395/12/18

Ethics committee reference number
IR.MUI.REC.1390.30947

Health conditions studied

1

Description of health condition studied
hypothermia and Shivering

ICD-10 code
T88.5

ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Core body temperature

Timepoint
Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until 30 minutes after the end of surgery.

Method of measurement
Tympanic thermometers

2

Description
blood pressure

Timepoint
Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until 30 minutes after the end of surgery.

Method of measurement
Blood Pressure Monitor (monitoring vital signs)

3

Description
pulse

Timepoint
Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until 30 minutes after the end of surgery.

Method of measurement
Pulse oximetry (monitoring vital signs)

4

Description
respiratory rate

Timepoint
Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until

30 minutes after the end of surgery.

Method of measurement

Counting (monitoring vital signs)

5

Description

oxygen saturation

Timepoint

Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until 30 minutes after the end of surgery.

Method of measurement

Pulse oximetry (monitoring vital signs)

6

Description

Shivering

Timepoint

after surgery

Method of measurement

Visual assessment scale

Secondary outcomes

1

Description

Duration of anesthesia

Timepoint

after suegery

Method of measurement

Since the induction of anesthesia until extubation

2

Description

intravenous fluids

Timepoint

after suegery

Method of measurement

Observation

3

Description

Duration of surgery

Timepoint

after suegery

Method of measurement

from making the surgical incision to skin closure and dressing

4

Description

pneumoperitoneum time

Timepoint

after suegery

Method of measurement

Since the introduction of gas into the abdomen until removing it from the abdomen

5

Description

The volume of carbon dioxide input

Timepoint

after suegery

Method of measurement

Observation

Intervention groups

1

Description

Patients immediately after induction of anesthesia under a forced air system with maximum temperature will be 45 ° C.

Category

Prevention

2

Description

Warming IV fluids (38 ° C) is recommended immediately after induction of anesthesia

Category

Prevention

3

Description

Control group receive routine care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Isfahan

Full name of responsible person

Fereshteh Baradaran Fard

Street address

Soffeh Blvd., Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Akram Aarabi

Street address

Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran

City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Fereshteh Baradaran Fard
Position
A graduate student in the operating room
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran
City
Isfahan
Postal code
Phone
+98 31 3792 7510
Fax
Email
baradaranfard.f@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Akram Aarabi
Position
University faculty member
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran
City
Isfahan
Postal code
Phone
+98 31 3792 7510
Fax
Email
aarabi@nm.mui.ac.ir
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty