

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the changes of body temperatures in laparoscopic and open surgeries. Single center, observational research

Protocol summary

Study aim

The primary aim of our research is; To compare the amount of change in body temperature in laparoscopic and open surgery applications. The secondary aim is to compare the frequency of hypothermia among these groups

Design

Observational research

Settings and conduct

The sublingual temperature of patients will be measured before anesthesia induction (standard intravenous induction and then inhalation anesthesia) every 5 minutes during surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who will undergo elective surgery for unilateral inguinal hernia, Society of Anesthesiology (ASA) risk group I-III, Between the ages of 18-65 Exclusion criteria: Patients with congenital or acquired neurological disease, Patients who are being treated for thyroid dysfunction, Patients whose body temperature was found to be below 36 °C before the start of the surgical procedure, Bilateral inguinal hernia surgery will be performed, Patients who require emergency surgery

Intervention groups

Patients who will undergo laparoscopic and open surgery practice training

Main outcome variables

To compare the amount of change in body temperature in laparoscopic and open surgery applications and the temperature measured each five-minutes during the surgical procedure

General information

Reason for update

data collection was terminated because sufficient number of patients was reached

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056453N1**

Registration date: **2023-03-26, 1402/01/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-31, 1402/05/09**

Update count: **1**

Registration date

2023-03-26, 1402/01/06

Registrant information

Name

guzin ceran

Name of organization / entity

Kirsehir training and research hospital

Country

Turkey

Phone

+90 386 213 45 15

Email address

gzncrn@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-01, 1401/10/11

Expected recruitment end date

2024-01-01, 1402/10/11

Actual recruitment start date

2023-02-01, 1401/11/12

Actual recruitment end date

2023-07-31, 1402/05/09

Trial completion date

empty

Scientific title

Comparison of the changes of body temperatures in laparoscopic and open surgeries. Single center, observational research

Public title

Comparison of the changes of body temperatures in laparoscopic and open surgeries. Single center, observational research

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who will undergo surgery for unilateral inguinal hernia Elective cases Society of Anesthesiology (ASA) risk group I-III Between the ages of 18-65

Exclusion criteria:

Patients with congenital or acquired neurological disease
Patients who are being treated for thyroid dysfunction
Patients whose body temperature was found to be below 36 °C before the start of the surgical procedure
Bilateral inguinal hernia surgery will be performed
Patients who require emergency surgery

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kirsehir ahi evran medical faculty ethics committee

Street address

Bağbaşı Mah. Sahir Kurutluoğlu Cad. No: 100 Merkez / KIRŞEHİR

City

kirsehir

Postal code

40200

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

2022-21/180

Health conditions studied

1

Description of health condition studied

hypothermia

ICD-10 code

T88.51

ICD-10 code description

Hypothermia following anesthesia

Primary outcomes

1

Description

To compare the amount of change in body temperature in laparoscopic and open surgery applications and the temperature measured each five-minutes during the surgical procedure

Timepoint

each five-minutes during the surgical procedure

Method of measurement

Body temperature measurements will be made sublingually during the surgical procedure with the temperature probe in Mindray Vato-Ex (Mindray, Beejing, China) monitor systems

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients who will undergo laparoscopic inguinal hernia surgery

Category

Early detection

2

Description

Intervention group: Patients who will undergo open technique inguinal hernia surgery

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Anaesthesiology and Reanimation, Kirsehir Training and Research Hospital

Full name of responsible person

güzin ceran

Street address

Kervansaray, 2019. Sk. No:1, 40200 Kirsehir
Merkez/Kirsehir

City

kirsehir

Postal code

40200

Phone

+90 506 163 09 36

Email

gzncrn@hotmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Department of Anaesthesiology and Reanimation, Ahi
Evrans University Faculty of Medicine

Full name of responsible person

recai dađlı

Street address

Bađbaşı, Şht. Sahir Kurutluođlu Cd. No: 100, 40100
Kirsehir Merkez/Kirsehir

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40100

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+90 542 653 69 75

Email

drresel@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Department of Anaesthesiology and Reanimation, Ahi
Evrans University Faculty of Medicine

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**

Department of Anaesthesiology and Reanimation,
Kirsehir Training and Research Hospital

Full name of responsible person

güzin ceran

Position

specialist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Phone

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available