Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial comparing the effect of using warm serums and non-heated serums during surgery on hypothermia, postoperative shivering and pain in patients after orthopedic surgery in lower extremities

Protocol summary

Summary

Aim of this study is survey effect of warm infusion serum and warm irrigation serum during surgery on postoperative hypothermia, shivering and pain in patients after major orthopedic surgery in lower extremities. Patients who administered for orthopedic surgery in lower extremities and have not any infection and metabolism disorders before surgery randomly assign in two groups. Sample size will be estimated after the pilot study. Patients in intervention group, will be received warm infusion serum and warm irrigation serum with temperature of 37.5 °C. Patients in control group will be received infusion serum and irrigation serum with temperature equal of operation room. Body temperature during surgery and at the end of recovery and severity of shivering in recovery room will be measured. Pain severity of surgical site in the first day will be measured every six hours. Then body temperature, severity of shivering and pain severity of patients in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052032361N2**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Hojjat Torkmandi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 263601135

Email address

torkmandi.or@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effect of using warm serums and non-heated serums during surgery on hypothermia, postoperative shivering and pain in patients after orthopedic surgery in lower extremities

Public title

Effect of using warm serums during surgery on post operative complications in patients after major orthopedic surgery in lower extremities

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: American society of anesthesiologist physical status class I or II; Age between 18 and 80

years; Time of surgery between 2 and 3 hours; Exclusion criteria: History of thyroid diseases; diabetes; infection before surgery; body Mass Index more than 35; temperature lower than 36°C and higher than 38°C before surgery; open fractures; blood transfusion during surgery; history of addiction; history of any orthopedic surgery in last month ago.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Nursing faculty, Semnan University of Medical Sciences, 5th Km of Damghan Road

City

Semnan

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.SEMUMS.REC.1396.65

Health conditions studied

1

Description of health condition studied

Hypothermia

ICD-10 code

T68

ICD-10 code description

T88.5

Primary outcomes

1

Description

Body temprature

Timepoint

Immediately after induction, 15 min after anesthesia, 30 min after anesthesia ,60 min after anesthesia and 120 min after anesthesia and at the end of surgery and in recovery room.

Method of measurement

By using tympanic thermometer Micro life IR100

Secondary outcomes

1

Description

Severity of shivering

Timepoint

In recovery room, every 15 min

Method of measurement

Shivering scale, every patient will be received score between 0 and 3

2

Description

Severity of pain

Timepoint

In the first day after surgery every 6 hours.

Method of measurement

By using of Visual Analog Scale (VAS) between 0-10

Intervention groups

1

Description

Intervention group: All patients will be received intravenous and irrigation serum with temperature of 37.5 °C during the surgery.

Category

Prevention

2

Description

Control group: All patients will be received intravenous and irrigation serum with temperature equal of operating room.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar hospital

Full name of responsible person
Hojjat torkmandi
Street address
Akhtar hospital, Sharifi manesh St, Elahieh
City
Tehran

2

Recruitment center
Name of recruitment center
Shahid Madani hospital
Full name of responsible person
Hojjat torkmandi
Street address
Shahid Madani hospital, North Taleghani Blv, Shahrak Edari
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Ali Rashydipoor
Street address
Semnan University of Medical Sciences, End of Basij Avenue, Semnan, Iran.
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
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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