

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 Rasydipoor

**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**

Semnan University of Medical Sciences

**Full name of responsible person**

Hojjat Torkmandi

**Position**

Student Master of critical care nursing

**Other areas of specialty/work****Street address**

Nursing faculty, Semnan University of Medical Sciences, 5th km Damghan road, Semnan, Iran.

**City**

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+98 23 3365 4191

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hojjat.or@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Semnan University of medical Sciences

**Full name of responsible person**

Hesamodin Askari Majdabadi

**Position**

Ph.D in Health Education and Promotion

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Hojjat Torkmandi

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Student master of critical care nursing

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hojjat.or@gmail.com

**Web page address**

## **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*