

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Different Warmer's Temperature on Core Temperature and Bleeding Rate in Patients Undergoing Posterior Spinal Fusion Surgery in Tehran Pars Hospital: Randomization Clinical Trial

Protocol summary

Study aim

The aim of this study is the comparison of the effect of two different warmer temperature levels on central temperature and bleeding rate in patients undergoing posterior spinal fusion surgery.

Design

In this study, patients will be undergoing entirely intravenous anesthesia in posterior spinal fusion surgery in Tehran Pars Hospital that will randomly be divided into two groups. The eligible patients will randomly be entered to one of the groups after signature of the consent. Sample size in this study is 90 patients.

Settings and conduct

This study will be performed on patients who have referred to Tehran Pars Hospital. The eligible patients will be undergoing entirely intravenous anesthesia in posterior spinal fusion surgery in Tehran Pars Hospital after signature of the consent. The patients will be divided randomly into two groups: A group: 38o C and B group: 40o C. In addition, all patients will be blinded about randomization and intervention of the study.

Participants/Inclusion and exclusion criteria

The inclusion criteria contain patients with risk of posterior spinal fusion surgery. In addition, the exclusion criteria include patients with ischemic heart disease; diabetes; kidney disease; hypertension; aging; infection; sepsis and coagulation disorders.

Intervention groups

Intervention group: The desired temperature in this group is 40° C. Comparison group: The desired temperature in this group is 38° C.

Main outcome variables

The primary outcome variables are serum level of hemoglobin, hematocrit and platelet counts, mean core temperature, mean arterial blood pressure, heart rate, and respiratory rate that will be recorded before, during and after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141225020434N2**

Registration date: **2017-12-20, 1396/09/29**

Registration timing: **retrospective**

Last update: **2017-12-20, 1396/09/29**

Update count: **0**

Registration date

2017-12-20, 1396/09/29

Registrant information

Name

gita fotoohi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

hassani.v@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Different Warmer's Temperature on Core Temperature and Bleeding Rate in Patients Undergoing Posterior Spinal Fusion Surgery in Tehran Pars Hospital: Randomization Clinical Trial

Public title

The effect of Different Warmer's Temperature on Core Temperature and Bleeding Rate in Patients Undergoing Posterior Spinal Fusion Surgery in Tehran Pars Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidates for posterior spinal fusion surgery

Exclusion criteria:

Ischemic Heart Disease Diabetic Patients Kidney Disease Hypertension Infection Disease Sepsis Coagulation Disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization will be conducted on individuals. Table of random numbers will be used for randomization .

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients will be blind to the intervention groups and randomization process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Iran. Tehran. Hemat Highway. Milad Tower

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2015-05-04, 1394/02/14

Ethics committee reference number

IR.IUMS.REC.1395.1218

Health conditions studied

1

Description of health condition studied

Patients undergoing posterior spinal fusion surgery

ICD-10 code

G32.8

ICD-10 code description

Other specified degenerative disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

Core temperature

Timepoint

Before, during and after surgery

Method of measurement

Thermometer

2

Description

Heart rate

Timepoint

Before, during and after surgery

Method of measurement

Monitor Vital Signs

3

Description

Respiratory rate

Timepoint

Before, during and after surgery

Method of measurement

Monitor Vital Signs

4

Description

Arterial blood pressure

Timepoint

Before, during and after surgery

Method of measurement

Monitor Vital Signs

5

Description

Hemoglobin

Timepoint

Before, during and after surgery

Method of measurement

Blood sample

6

Description

Hematocrit and platelet

Timepoint

Before, during and after surgery

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

The warmer will set at 40°C for the intervention group during surgery. The anesthesia protocol for both groups will consist of premedication with 0.05 mg/kg midazolam, induction by 5 mg/kg thiopental Sodium, 0.3 mg/kg atracurium, and 100% oxygen.

Category

Prevention

2

Description

Comparison group: The temperature in this group is 38 °C

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Pars general hospital

Full name of responsible person

Giti Fotohi

Street address

No11, Saeedi Alley, Fereshteh St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malekoti

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Valiolla Hasani

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable