Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of forced air warming and warmed intravenous fluid on comfort and prevention of shivering after spinal anesthesia in patient undergoing orthopedic surgery

Protocol summary

Study aim
Comparison the effect of forced air warming and warmed intravenous fluid on comfort and prevention of shivering after spinal anesthesia in patient undergoing orthopedic surgery

Design
A clinical trial with a control group, with parallel groups,single Blind , randomized

Settings and conduct
The present study will be performed in Kashan Naghavi Hospital operating room. Patients referred to the operating room of the lower extremity for orthopedic surgery will be randomly divided into three groups: hot air pressure (40 patients), warm venous serum (40 patients) and control group (40 patients). The first group will receive the serum at room temperature (21-23 ° C) and warm air at 38 ° C. For the second group, the warm serum will be infused at 37 ° C. The third group is the control group, which will be routinely monitored for serum and room temperature (21-23 ° C).

Participants/Inclusion and exclusion criteria
Patients undergoing orthopedic surgery - age 18-60 years - under spinal anesthesia

Intervention groups
Group A (using of forced air warming 38° C) Group B (using warm intravenous serum at 37° C) Group C (The control group will be routinely monitored for serum and room temperature)

Main outcome variables
Reduce shivering during surgery, reduce drug side effects, earlier discharge, reduce anxiety, reduce hospital costs.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191224045885N1**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **prospective**

Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

Registrant information

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Mehdi Moheb

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-05, 1398/12/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of forced air warming and warmed intravenous fluid on comfort and prevention of shivering

after spinal anesthesia in patient undergoing orthopedic surgery

Public title
The effect of forced air warming and warmed intravenous fluid on comfort and prevention of shivering

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Having orthopedic surgery in the lower limb and under spinal anesthesia Having the consent to participate in the study Patients who are in Class 1 and 2 according to the American Anesthesiological Association (ASA) Patients 18-60 years old No corticosteroid drugs and NSAIDs taken 24 hours before surgery

Exclusion criteria:
Blood injection and blood products during surgery Conversion of spinal anesthesia to general anesthesia during surgery due to insufficient surface area and severity of anesthesia The temperature of the tympanic membrane is less than 36.5 and greater than 37.5 ° C Increased spinal anesthesia Duration of surgery more than 3 hours

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided into 6 groups and divided into three groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, all three groups of participants were kept blind. Patients will be told that the study is intended for your well-being so that they will experience comfortable environmental surgery.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences

Street address
15 Khordad Square, Municipality street

City
Kashan

Province
Isfehan

Postal code
8715973474

Approval date
2019-06-30, 1398/04/09

Ethics committee reference number
IR.Kaums.nuhepm.rec.1398.022

Health conditions studied

1

Description of health condition studied
Patients undergoing orthopedic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Patients' shivering based on quadratic scale: No shiver 0; Mild shiver: Mild contractions in facial and neck muscles (1); Moderate shiver: Apparent shivering in neck and shoulders and extremities (2); Severe shivering: Apparent shivering They will be evaluated throughout the body (3)

Timepoint
On arrival before spinal (0 minutes), 15 minutes after spinal, surgical completion time, recovery time, and 15 minutes after surgery

Method of measurement
Quadruple shivering Scale

Secondary outcomes

1

Description
Patients' comfort ratings will be scored based on a VAS observation score ranging from 0 to 10. (0 indicates patient satisfaction with temperature and temperature; and 10 indicates worst patient perception of temperature and temperature conditions)

Timepoint
On arrival before spinal (0 minutes), 15 minutes after spinal, surgical completion time, recovery time, and 15 minutes after surgery

Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: The first group of serum recipients will be operated at room temperature (21-23 ° C) and hot air at 38 ° C (Warm Touch; Mallinckrodt Medical, St Louis, MO, USA).
Category
Prevention

2

Description
Intervention group: For the second group, 37 ° C warm serum kept in the heater prior to infusion (Fan Azma Gostar.CO, Iran; Thermometer Industrial Group) to reach 37 ° C during infusion.
Category
Prevention

3

Description
Control group: The third group is the control group that will be under routine care of serum and room temperature (21-23 ° C).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Hospital
Full name of responsible person
Firouzian Ali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Kashan University of Medical Sciences
Proportion provided by this source
80
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
Kashan University of Medical Sciences
Full name of responsible person
Moheb Mehdi
Position
Anesthesiologist
Latest degree
Bachelor
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after unidentifiable people.

When the data will become available and for how long
Start access period 7 months after publishing results.

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
Compliance with the rules is not a restriction on the use of data.

From where data/document is obtainable
Kashan University of Medical Sciences-Tel: 03155540021 Email: info@kaums.ac.ir

What processes are involved for a request to access data/document
Access period starting from September 1999 through Kashan University of Medical Sciences

Comments