Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of iIntravenous Injection of Serum temperature on hemoglobin saturation with oxygen, hemodynamic changes, shivering and postoperative recovery time in patients under general anesthesia and spinal anesthesia in subjects aged 16 to 55 years

Protocol summary

Study aim
Identifying and preventing postoperative complications
Design
Factorial and with blinded
Settings and conduct
The hospitals affiliated to the Babol University of Medical Sciences
Participants/Inclusion and exclusion criteria
People should be between the ages of 16 and 55 an undergo lower orthopedic surgery; The patient has Underlying problems such as obesity, vascular problems, pregnancy and anemia.
Intervention groups
Injection serum temperature
Main outcome variables
Have no consequences

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100908004715N2**
Registration date: **2019-01-19, 1397/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**
Update count: **0**
Registration date
2019-01-19, 1397/10/29

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-08-23, 1397/06/01
Expected recruitment end date
2019-02-20, 1397/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of iIntravenous Injection of Serum temperature on hemoglobin saturation with oxygen, hemodynamic changes, shivering and postoperative recovery time in patients under general anesthesia and spinal anesthesia in subjects aged 16 to 55 years

Public title
The effect of temperature of Intravenous Injection of Serum on postoperative shivering
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
All patient aged 16 to 55 years undergoing orthopedic surgery are lower extremity. The patients surgery should

last longer than 1 hour and be used for general anesthesia or spinal anesthesia.

Exclusion criteria:

The patient has Underlying problems such as obesity, vascular problems، pregnancy and anemia.

Age

From **16 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this project, 200 patients are selected as samples, divided into two equal groups of 100 general anesthesia and spinal anesthesia. Each group of 100 people is divided into two groups of 50 cases and controls.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Babol University of Medical Sciences

Street address

Mazandaran, Babol, Ganj Afrouz Avenue, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.MUBABOL.REC.1397.034

Health conditions studied

1

Description of health condition studied

Shivering after operation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemoglobin saturation with oxygen, postoperative shivering and hemodynamic changes

Timepoint

In the first hour, every 15 minutes and up to 4 hours after surgery, every 1 hour once

Method of measurement

Warmers and thermocouple

Secondary outcomes

1

Description

Age and sex and type of anesthesia and patient body temperature

Timepoint

Before surgery

Method of measurement

Through the questionnaire

Intervention groups

1

Description

In this study, 100 patients between the ages of 16 and 55 undergoing lower limb orthopedic surgery with general anesthesia or spinal anesthesia, with the duration of surgery of more than one hour, were randomly assigned to two groups of 50. The first group, including the general anesthesia group, and spinal anesthesia, with angiocath No18 through the elbow vein of the 1 ml of blood loss 3 ml dextrose saline crystalloid, plus 2 ml per kg body weight, is injected as a preservative dose from the same dextrose saline crystalloid. Blood is also prescribed if the patient's bleeding is more than 15% of the body's blood volume. Liquids administered to the patient (serum and blood) are injected through a fluid heater (warmer) at 37 C.

Category

Prevention

2

Description

In this study, 100 patients between the ages of 16 and 55 undergoing lower limb orthopedic surgery with general anesthesia or spinal anesthesia, with the duration of surgery of more than one hour, were randomly assigned to two groups of 50. The first group,

including the general anesthesia group, and spinal anesthesia, with angiocath No18 through the elbow vein of the 1 ml of blood loss 3 ml dextrose saline crystalloid, plus 2 ml per kg body weight, is injected as a preservative dose from the same dextrose saline crystalloid. Blood is also prescribed if the patient's bleeding is more than 15% of the body's blood volume. With the exception that in the control group, the dextrose saline crystalloid and the blood may be administered at the same operating temperature (22 C). After the operation, Intervention and control group evaluated for the Hemoglobin saturation with oxygen, hemodynamic changes, shivering and recovery time. The operation temperature is checked by thermometer.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Mr.Akbar Zadeh
Street address
Ganj Afrouz Avenue, Babol, Mazandaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
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
Babol University of Medical Sciences
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
Babol University of Medical Sciences
Full name of responsible person
Yousef Mortazavi
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

After completing the project, all information will be provided

When the data will become available and for how long

At least two months after the completion of the project

To whom data/document is available

All employees and students at hospitals and medical universities

Under which criteria data/document could be used

After asking the parson and confirming all the executives of the project

From where data/document is obtainable

Send mail to the messenger

What processes are involved for a request to access data/document

After sending an email, administrators can respond whithin a maximum of two weeks to one month

Comments