

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of Intravenous 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 and 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

##### Name

Yosof Mortazavi

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1223 4142

##### Email address

y.mortazavi@mubabol.ac.ir

##### 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 Intravenous 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

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-47745

##### Phone

+98 11 3220 8143

##### Email

y.mortazavi@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr Jalali

##### Street address

Ganj Afrouz Avenue, Babol, Mazandaran

##### City

Babol

##### Province

Mazandaran

##### Postal code

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##### Phone

+98 11 3220 8143

##### Email

y.mortazavi@mubabol.ac.ir

##### 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

Master

##### Other areas of specialty/work

Anesthesiology

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Yousef Mortazavi

##### Position

Associate professor

##### Latest degree

Master

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

yousef mortazavi

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

Anesthesiology

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Babol

**Province**

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**Postal code**

4717647745

**Phone**

+98 11 3219 5520

**Email**

mortazavi1337@yahoo.com

## 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 within a maximum of two weeks to one month

**Comments**