

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of hot forced-air system and warm intravenous serum with routine (blanket) method on hemodynamic parameters, shivering and waking time in the elderly undergoing open heart surgery

#### Protocol summary

##### Study aim

Comparison of the effect of hot compressed air system; warm intravenous serum and routine (blanket) method on hemodynamic parameters, shivering and waking time in the elderly undergoing open heart surgery

##### Design

Clinical trial with control group, with parallel groups, single-blind, phase 3 on 90 patients. A randomized controlled block was used for randomization.

##### Settings and conduct

Study place: Ayatollah Rouhani Hospital, BABOL, ICU Department of Cardiology, male and female patients over 60 years old, eligible candidates for heart surgery in 1400; Type of blinding: one side blind; How to blind: patients are not aware of being in the intervention or control group

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 60 years old; Having esophageal temperature less than 36 degrees Celsius (based on the thermal sensor of Saadat monitoring); Cardiac output (EF) greater than 40%; Non inclusion criteria: addiction to several drugs; pre-operative renal and hepatic insufficiency; Receiving high-dose inotropic drugs (epinephrine, norepinephrine), antiarrhythmics (lidocaine) before the patient enters the ward; Ascending aortic dissection surgery, Bental surgery

##### Intervention groups

Intervention group 1: receiving forced-air warming system with WARM TOUCH system with WARM TOUCH NELLCON brand (2012); Intervention group 2: receiving warm intravenous serum with temperature Physiologically it will be infused at 37-40 ° C; Control group: In patients of routine care, a normal blanket will be used until the central temperature reaches above 37 degrees.

##### Main outcome variables

Blood pressure; heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220310054240N1**

Registration date: **2022-04-06, 1401/01/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-06, 1401/01/17**

Update count: **0**

##### Registration date

2022-04-06, 1401/01/17

##### Registrant information

##### Name

Mohamad Bagher Abarpour Roushan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3220 8143

##### Email address

akbarpour.mb9560@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-06, 1400/12/15

##### Expected recruitment end date

2022-07-21, 1401/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of hot forced-air system and warm intravenous serum with routine (blanket) method on hemodynamic parameters, shivering and waking time in the elderly undergoing open heart surgery

## Public title

Comparison of the effect of using forced-air warming system, warm intravenous serum with normal blanket on chills and waking time in the elderly undergoing open heart surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All elderly patients (over 60 years old) are candidates for open heart surgery at Ayatollah Rouhani Hospital in Babol Having an esophageal temperature of less than 36 ° C Cardiac output (EF) greater than 40%

### Exclusion criteria:

multidrug addiction Preoperative renal and hepatic insufficiency sensory-motor disorders such as Guillain-Barré syndrome or myasthenia gravis Receiving high-dose inotropic drugs (epinephrine, norepinephrine), antiarrhythmics (lidocaine) before the patient enters the ward Ascending aortic dissection surgery, Bental surgery

## Age

From **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Assignment of patients in three groups will be simple randomly. One of the colleagues who will not participate in the measurement of patients' clinical indicators, determine random allocation of the patients to one of three intervention groups (Group 1: forced-air warming system Group II : Warm intravenous serum) or control (group 3: use a regular blanket) by throwing coins.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Due to the research conditions, it is not possible to perform complete blinding. The study is single blind (patients are not aware of being in the intervention or control group). Because patients are not awake when they enter the intensive care unit, it is not possible for them to be aware of being in the control or intervention group. Patients wake up at least three hours after entering the ward, which coincides with the end of the intervention.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Health Research Institute - Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences; Ganj Afroz Street

##### City

Babol

##### Province

Mazandaran

##### Postal code

47745 - 47176

#### Approval date

2022-03-06, 1400/12/15

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.256

## Health conditions studied

### 1

#### Description of health condition studied

open heart surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

At the beginning of the study, up to 6 hours (on arrival, first hour, second hour, ... sixth hour) will be recorded from the time of entering the ICU until waking up.

#### Method of measurement

Sphygmomanometer

### 2

#### Description

Heart rate

#### Timepoint

At the beginning of the study, up to 6 hours (on arrival, first hour, second hour, ... sixth hour) will be recorded from the time of entering the ICU until waking up.

#### Method of measurement

According to the checklist will be evaluated up to 6 hours until waking up.

### 3

#### **Description**

Respiration Rate

#### **Timepoint**

At the beginning of the study, up to 6 hours (on arrival, first hour, second hour, .... sixth hour) will be recorded from the time of entering the ICU until waking up.

#### **Method of measurement**

According to the checklist will be evaluated up to 6 hours until waking up.

### 4

#### **Description**

Arterial Blood Gases

#### **Timepoint**

At the beginning of the study, up to 6 hours (on arrival, first hour, second hour, .... sixth hour) will be recorded from the time of entering the ICU until waking up.

#### **Method of measurement**

According to the checklist will be evaluated up to 6 hours until waking up..

### 5

#### **Description**

Shivering

#### **Timepoint**

From the time the patient enters the ICU until he or she regains consciousness, every 15 minutes to 6 hours (on arrival, 15 minutes, 30 minutes, 45 minutes, 60 minutes ..... and 360 minutes) will be examined.

#### **Method of measurement**

Crossley and Mahajan shivering benchmark evaluation methods

### 6

#### **Description**

Waking time

#### **Timepoint**

From the time the patient enters the ICU until he or she regains consciousness, every 15 minutes to 6 hours (on arrival, 15 minutes, 30 minutes, 45 minutes, 60 minutes ..... and 360 minutes) will be examined.

#### **Method of measurement**

RAMSAY SEDATION SCORE (RSS) Assessment Method (Awakening Assessment)

## **Secondary outcomes**

### 1

#### **Description**

nausea

#### **Timepoint**

Upon arrival of the patient in the ICU until waking up every hour for 6 hours (on arrival, first hour, second hour .... and sixth hour)

#### **Method of measurement**

Based on checklist

### 2

#### **Description**

vomiting

#### **Timepoint**

Upon arrival of the patient in the ICU until waking up every hour for 6 hours (on arrival, first hour, second hour .... and sixth hour)

#### **Method of measurement**

Based on checklist

### 3

#### **Description**

Dispenea

#### **Timepoint**

Upon arrival of the patient in the ICU until waking up every hour for 6 hours (on arrival, first hour, second hour .... and sixth hour)

#### **Method of measurement**

Based on checklist

### 4

#### **Description**

arrhythmias

#### **Timepoint**

Upon arrival of the patient in the ICU until waking up every hour for 6 hours (on arrival, first hour, second hour .... and sixth hour)

#### **Method of measurement**

Based on checklist

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Warm compressed air heating system with Warm Touch brand (medical equipment) with temperature between 42-38 ° C through NELLCOR WARM TOUCH 501-5900 (2011) will be used for patients undergoing open heart surgery when entering the ICU, for 4-5 hours.

#### **Category**

Treatment - Devices

### 2

#### **Description**

Intervention group 2: warm intravenous serum, one liter per hour with physiological temperature at 40-37 ° C

#### **Category**

Treatment - Other

### 3

#### **Description**

Control group: Ordinary blanket produced by a special brand in two layers with dimensions (114 by 175 cm) that covers from the armpits to the toes.

#### **Category**

Treatment - Devices

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Ayatollah Rouhani Hospital; Babol University of Medical Sciences

**Full name of responsible person**

Zahra Fotokian

**Street address**

Babol University of Medical Sciences; Ganj Afrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3219 9592

**Fax**

+98 11 3219 0181

**Email**

akbarpour.mb9560@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Mehdi Rajabnia

**Street address**

Babol University of Medical Sciences; Ganj Afrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3219 7667

**Email**

ramazan@yahoo.com

**Grant name**

University Research Council

**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**

Mohamad Bagher Akbarpour Roushan

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Babol University of Medical Sciences; Ganj Afrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3219 9592

**Fax**

+98 11 3219 0181

**Email**

akbarpour.mb9560@gmail.com

**Web page address**

<http://mubabol.ac.ir>

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Zahra Fotokian

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Babol University of Medical Sciences; Ganj Afrooz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3219 9592

**Fax**

+98 11 3219 0181

**Email**

zfotoukian@yahoo.com

**Web page address**

http://mubabol.ac.ir

**Fax**

+98 11 3219 0181

**Email**

pamrimaleh@yahoo.com

**Web page address**

http://mubabol.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Parviz Amri Melah

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Babol University of Medical Sciences; Ganj Afrooz  
Road

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3219 9592

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The type of study is a clinical trial and the information must be ethically confidential.

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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