

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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Babol University of Medical Sciences; Ganj Afrooz Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Other areas of specialty/work

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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