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

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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 Afrooz 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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Sponsors / Funding sources

1

Sponsor

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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
Bachelor

Other areas of specialty/work
Nursery

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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