Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of using Forced Hot Air System on physiological parameters, waking time and arterial blood gases in patients undergoing coronary artery bypass grafting surgery in Bushehr heart hospital in 2019

Protocol summary

Study aim

The effect of using compressed air system on physiological parameters, time of awakening and arterial blood gas in patients undergoing coronary artery bypass graft surgery in Bushehr Heart Hospital

Design

Clinical trial with control group, with parallel groups, randomized controlled block, single blind

Settings and conduct

This study will be carried out at Bushehr Heart Hospital. Eligible male and female cardiac patients undergoing elective coronary artery bypass surgery in 1398 will be included in the study. Patients will then be randomly assigned to one of two groups receiving either warm compressed air or routine care. ABG and physiologic data (patient ICU admission and patient awakening) data, FOUR Score Assessment results (from patient admission to ICU, patient response to verbal, visual, and auditory stimulation every 15 minutes) Will be collected in a checklist designed by the researcher. Description of Blindness: For the control group, the compressed air system is used if the patient's perception is the opposite.

Participants/Inclusion and exclusion criteria

Entry requirements: Being at least 18 years old Having a tympanic temperature below 36 ° C EF (ejection fraction) greater than 40% Exclusion criteria: Sensory-motor disorder such as patients with Guillain Barre or Myasthenia gravis Inflammation, pus excretion or discharge into the ear canal or ear injuries Patient restlessness If drainage exceeds 100 cc / hr in the ICU ward for more than 4 hours Take high-dose inotropic drugs Re surgery (Reexploration) to control bleeding Patients with diagnosis of M.S and A.S (mitral and aortic stenosis) Severe anemia (hemoglobin less than 8)

Intervention groups

Intervention group:Receiver for hot compressed air heating system (Warm Touch brand (u WT Model COVIDIEN6000))

Main outcome variables

Physiological indicators Time to wake up after surgery Arterial Blood Gas Parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190809044488N1**
Registration date: **2020-01-13, 1398/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-13, 1398/10/23**
Update count: **0**

Registration date

2020-01-13, 1398/10/23

Registrant information

Name

Sharif Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3344 5173

Email address

sharif.sharifi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-07, 1398/06/16

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of using Forced Hot Air System on physiological parameters, waking time and arterial blood gases in patients undergoing coronary artery bypass grafting surgery in Bushehr heart hospital in 2019

Public title

Effects of using Forced Hot air system on physiological parameters, waking time and arterial blood gases in patients undergoing coronary artery bypass grafting surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being at least 18 years old Having a tympanic temperature below 36 ° C EF (ejection fraction) greater than 40%

Exclusion criteria:

Sensory-motor disorder such as patients with Guillain Barre or Myasthenia gravis Inflammation, pus excretion or discharge into the ear canal or ear injuries Patient restlessness If drainage exceeds 100 cc / hr in the ICU ward for more than 4 hours Take high-dose inotropic drugs Resurgery (Reexploration) to control bleeding Patients with diagnosis of M.S and A.S (mitral and aortic stenosis) Severe anemia (hemoglobin less than 1)

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use Simple Random Sampling to allocate patients in groups. A colleague who will not perform any clinical measurements on study subjects, will use a coin-flip to randomly assign study subjects to either intervention (hot compressed air system) and control (ordinary blankets) groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the research conditions full blindness is impossible. The study is single-blind (Patients are not aware of being in the intervention or control group).Because patients are not awake at the time of admission to the intensive care unit, it is not possible for them to be aware of either of the control or intervention groups are included. Patient awakening occurs after at least three hours of admission to the intensive care unit and this coincides with the time of completion of the Intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bushehr University of Medical Sciences

Street address

Bushehr Sabzabad- Bushehr University of Medical Sciences- Pardis site- Next to Salman Farsi Hospital.

City

Bushehr

Province

Boushehr

Postal code

7565184345

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.BPUMS.REC.1398.061

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Physiological indicators

Timepoint

The time the patient enters the ICU and the time the patient regains consciousness

Method of measurement

check list

2

Description

Time to wake up after surgery

Timepoint

The patient's response to verbal, visual, and auditory stimulation is monitored every 15 minutes since the patient's arrival in the ICU.

Method of measurement

FOUR Score evaluation method

3

Description

Arterial Blood Gas Parameters

Timepoint

The time the patient enters the ICU and the time the patient regains consciousness

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Receiver for hot compressed air heating system (Warm Touch brand (u WT Model COVIDIEN6000))

Category

Treatment - Devices

2

Description

Using a plain blanket (from a specific brand in two-dimensional (114 by 175 cm) layers covering the armpit to the toe) to warm the patient after surgery

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr Heart Hospital

Full name of responsible person

Soheila Esfandiari, MSc Nursing Student

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Bushehr, Teacher Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Sharif Sharifi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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