Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of rewarming on hemodynamic parameters and cognitive state in patients after open heart surgery

Protocol summary

Study aim

Determination of the effect of rewarming on hemodynamic parameters and cognitive state in patients after open heart surgery

Design

In this clinical trial, single blind, with two parallel randomized groups, patients who are candidates for open-heart surgery were selected through convenient sampling and were divided into two control(n=40) and intervention(n=40) groups through block randomization (block size of 4).

Settings and conduct

The intervention will begin after entering the patient to the ICU with an electric blanket. Warming will last until the patient's body temperature reaches a normothermic level(37-37.5). The control group will receive routine care.Participant and the person who will analyses the data are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent, MMSE score of more than 24 at beginning, candidates for elective Open-Heart surgery, Not having Intra-Aortic Balloon Pump before surgery. Exclusion criteria: Prolongation of intubation (more than 12), opened chest for postoperative reasons, having intra-aortic balloon after surgery, post-operative re-intubation, aneurysm or aortic dissection surgery, death, return to the operating room, prolongation of surgery(more than 5), emergency open heart surgeries

Intervention groups

The intervention is rewarming the patients by electric blanket after open heart surgery until the body temperature reaches to 37-37.5.Routine care is done in the control group .

Main outcome variables

Heart rate; systolic blood pressure; diastolic blood pressure; mean arterial pressure; central venues pressure; drainage; urinary output;cognitive state

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100124003146N8**
Registration date: **2019-10-19, 1398/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-19, 1398/07/27**
Update count: **0**

Registration date

2019-10-19, 1398/07/27

Registrant information

Name

Ismail Azizi-Fini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

azizi-es@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-21, 1398/05/30

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of rewarming on hemodynamic parameters and cognitive state in patients after open heart surgery

Public title
The effect of rewarming on hemodynamic parameters and cognitive state in patients after open heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent for participating in study Gaining MMSE score of more than 24 at the beginning of the study Patients candidate for elective Open-Heart surgery Not having Intra-Aortic Balloon Pump before the surgery
Exclusion criteria:
Prolongation of intubation (more than 12 hours) for respiratory problems Opened chest for postoperative reasons Having Intra-Aortic Balloon Pump after the surgery post-operative re-intubation Patients who underwent the surgery of aneurysm or dissection of aorta patient death Return to operating room for any reason Prolonged surgery for more than 5 hours Patients undergoing emergency open heart surgery
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were randomly assigned to experimental and control groups by block randomization (via software) with 4 blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
Because patients have low level of consciousness and are intubated, they are not aware of the type of intervention and are blind. On the other hand, the person who analyzes the results of the study is not aware of the intervention or control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Kashan University of Medical Sciences
Street address
5th kilometer Qotb Ravandi blouvar
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2019-07-01, 1398/04/10
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1398.016

Health conditions studied

1

Description of health condition studied
Hemodynamic parameters of the patient undergoing open heart surgery- cognitive state of the patient undergoing open heart surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
mean arterial pressure
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every 30 minutes (at the first hour of intervention), every hour (for 4 hours after the intervention)
Method of measurement
monitor

2

Description
Systolic blood pressure
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every 30 minutes (at the first hour of intervention), every hour (for 4 hours after the intervention)
Method of measurement
monitor

3

Description
Diastolic blood pressure

Timepoint
Before the intervention at the time of entering of the patient to the ICU, every 30 minutes (at the first hour of intervention), every hour (for 4 hours after the intervention)
Method of measurement
monitor

4

Description
Central venous pressure
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every 30 minutes (at the first hour of intervention), every hour (for 4 hours after the intervention)
Method of measurement
monitor

5

Description
Heart rate
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every 30 minutes (at the first hour of intervention), every hour (for 4 hours after the intervention)
Method of measurement
monitor

6

Description
temperature
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every 30 minutes (at the first hour of intervention), every hour (for 4 hours after the intervention)
Method of measurement
temperature probe of monitor

7

Description
Urine output
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every hour (for 4 hours after the intervention)
Method of measurement
urinary bag

8

Description
drainage
Timepoint
Before the intervention at the time of entering of the patient to the ICU, every hour (for 4 hours after the intervention)
Method of measurement
Drainage bottle

9

Description
cognitive state
Timepoint
Before the intervention and one week after surgery
Method of measurement
MMSE questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use of a warm mattress at the time of entering the patient to intensive care unit until the body temperature reaches 37 ° C after open heart surgery.in this method , for warming the patient, E U 133 (Electric Under blanket with heating) will be used which has the power of W75. the size of the product is about 150* 80 cm . temperature setting has three level index , which is switched off automatically after three hours , warms fast and the most heat is in the foot
Category
Treatment - Devices

2

Description
Control group: control group will receive the routine care after open heart surgery.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Somayeh Hajijafari
Street address
Ravand Ave., Parastar Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
Street address
Ravand Ave., Parastar Blvd.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Esmail Azizi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
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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

There is no more information.

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