Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of hypothermia on electrolyte changes in adult patients undergoing open heart surgery

Protocol summary

Study aim
determination of the effects of hypothermia on electrolyte changes in adult patients undergoing open heart surgery

Design
a clinical trial with control group, parallel groups, single blinded, made as accident using a random number table, sample size of a whole of sixty people of whom 30 people were put in each group.

Settings and conduct
the study was done in Sari Fateme Zahra Hospital. all the patient's were operated on by a heart surgeon. after obtaining informed consent the patients were randomly put in the two groups of hypothermia and normothermia without knowledge of which group they were put in. in the hypothermia group the patient's body temperature is brought down to 30°c, in the normothermia group the patient's body temperature naturally comes down to 35° c. the blood sodium, potassium, and calcium levels were measured and recorded in the preoperative stages, one day after the operation and the day of ICU discharge.

Participants/Inclusion and exclusion criteria
Entry conditions : adult patients of ages 40 to 85; being eager to study; residence in mazandaran; lack of psychological disorders Exit conditions : usage of depression drugs; a lack of interest in going on with the study; valve replacement at the same time as CABG; people in need of emergency surgery

Intervention groups
in the hypothermia group the patient's body temperature is brought down to 30°c and topical cooling is also used. in the normothermia group the patient's body temperature naturally comes down to 35°c.

Main outcome variables
any electrolyte disturbances of too high or too low of sodium(135 to 145 mEq/L) are known as hyponatremy and hypernatremy . electrolyte disturbances of too high or too low of potassium(3/5 to 5/5 mEq/L) are known as hypokalemia and hyperkalemia. electrolyte disturbances of too high or too low of calcium(8/5 to 10/2 mEq/L) are known as hypocalcaemia and hypercalcaemia.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190719044273N1**
Registration date: **2019-09-03, 1398/06/12**
Registration timing: **retrospective**

Last update: **2019-09-03, 1398/06/12**
Update count: **0**

Registration date
2019-09-03, 1398/06/12

Registrant information
Name
Hodeise Asadpour sorkhkolaee
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
2019-05-22, 1398/03/01
Expected recruitment end date
2019-07-23, 1398/05/01
Actual recruitment start date
2019-06-18, 1398/03/28
Actual recruitment end date
2019-08-11, 1398/05/20

Trial completion date
2019-08-11, 1398/05/20

Scientific title
The effect of hypothermia on electrolyte changes in adult patients undergoing open heart surgery

Public title
The effect of hypothermia on electrolyte changes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients of ages 40 to 85 Being eager to study Residence in mazandaran Lack of psychological disorders
Exclusion criteria:
Usage of depression drugs A lack of interest in going on with the study Valve replacement at the same time as CABG People in need of emergency surgery
Age
From **40 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were taken by the availability method, and all the patients who met the conditions of the study were picked, samples were taken of two groups of hypothermia and normothermia randomly chosen patients by using a random number table.
Blinding (investigator's opinion)
Single blinded
Blinding description
After explaining the study and obtaining informed consent from the participants, they were not informed of the group they were put in.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sari University of Medical Sciences
Street address
Next to 13aban pharmacy, MOallem sq
City
Sari
Province
Mazandaran
Postal code
4843161399
Approval date
2019-06-18, 1398/03/28
Ethics committee reference number
IR.MAZUMS.REC.1398.575

Health conditions studied

1

Description of health condition studied
Coronary heart diseases
ICD-10 code
I20-I25
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
any electrolyte disturbances of too high or too low of sodium(135 to 145 milliequivalent per liters) are in order known and registered as electrolyte hyponatremy and hypernatremy disturbances.
Timepoint
measurements were taken at times before surgery, one day after surgery and the day of discharge from ICU
Method of measurement
a study of blood samples in the lab

2

Description
any electrolyte disturbances of too high or too low of potassium(3/5 to 5/5 milliequivalent per liters) are in order known and registered as electrolyte hypokalemia and hyperkalemia disturbances.
Timepoint
measurements were taken at times before surgery, one day after surgery and the day of discharge from ICU
Method of measurement
a study of blood samples in the lab

3

Description
any electrolyte disturbances of too high or too low of calcium(8/5 to 10/2 milliequivalent per liters) are in order known and registered as electrolyte hypocalcaemia and hypercalcaemia disturbances.
Timepoint
measurements were taken at times before surgery, one

day after surgery and the day of discharge from ICU

Method of measurement

a study of blood samples in the lab

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the hypothermia group the patient's body temperature is brought down to 30°c and topical cooling is also used.

Category

Treatment - Other

2

Description

Control group: in the normothermia group the patient's body temperature naturally comes down to 35°c.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh Zahra hospital

Full name of responsible person
Soleiman MOslemipour

Street address
Next to Sari blood transfusion center, Artesh Blvd., Emam Hossein Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Majid Saeedi

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Payambare Azam academic center, Khazarabad Ave., Khazar sq.

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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
Sari 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
Mazandaran University of Medical Sciences

Full name of responsible person
Hodeise Asadpoursorkhkolaee

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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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