

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 sorkhkolae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3328 4731

##### Email address

hodeiseasadpour1995@gmail.com

##### 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.

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

13371-48188

##### **Phone**

+98 11 3332 3024

##### **Email**

Hodeiseasadpour1995@gmail.com

#### **Sponsors / Funding sources**

##### **1**

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Majid Saeedi

##### **Street address**

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

#### **City**

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#### **Province**

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#### **Postal code**

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#### **Phone**

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#### **Email**

Majsaeedi@gmail.com

#### **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 Asadpoursorkhkolae

##### **Position**

Student

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Nursery

##### **Street address**

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#### **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hooshang Akbari

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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

**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hodeise ASadpoursorkhkolae

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**