

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of different patient cooling on blood sugar in open heart surgery

Protocol summary

Study aim

Determining the effect of cooling the patient with different degrees on blood sugar levels in open heart surgery

Design

Patients will be divided into two groups so that the temperature of one group will reach 30 degrees Celsius and the temperature of the other group will reach 34 degrees Celsius. At the target temperature of group 1 to 30 degrees Celsius and group 2 to 34 degrees Celsius, finally before the patient warms up, blood sugar will be measured and recorded again and blood sugar values in two groups of 30 degrees Celsius and 34 degrees Celsius will be compared.

Settings and conduct

Patients will be divided into two groups so that the temperature of one group will reach 30 degrees Celsius and the temperature of the other group will reach 34 degrees Celsius. At the target temperature of group 1 to 30 degrees Celsius and group 2 to 34 degrees Celsius, finally before the patient warms up, blood sugar will be measured and recorded again and blood sugar values in two groups of 30 degrees Celsius and 34 degrees Celsius will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patient informed consent Patients undergoing coronary artery bypass grafting (CABG) and heart valve surgery. • Non-diabetic patients • Patients with normal fasting blood sugar (up to 100 mg / dL)
Criteria for not entering: Patients undergoing CABG without a cardiopulmonary pump. • Diabetic patients • Patients with abnormal fasting sugar (more than 100 mg / dL)

Intervention groups

The temperature of one group will reach 30 degrees Celsius and the temperature of the other group will reach 34 degrees Celsius

Main outcome variables

Temperature, Blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220404054406N1**

Registration date: **2022-04-17, 1401/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-17, 1401/01/28**

Update count: **0**

Registration date

2022-04-17, 1401/01/28

Registrant information

Name

fatemeh mohammadi shahrestanaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3322 9222

Email address

mohammadifatemeh63813@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-10, 1401/01/21

Expected recruitment end date

2022-05-11, 1401/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of different patient cooling on blood sugar in open heart surgery

Public title
The effect of different patient cooling on blood sugar in open heart surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patient informed consent Patients undergoing coronary artery bypass grafting (CABG) and heart valve surgery. Non-diabetic patients Patients with normal fasting blood sugar (up to 100 mg / dL)
Exclusion criteria:
Patients undergoing CABG surgery without a cardiopulmonary pump. Diabetic patients Patients with abnormal fasting blood sugar (more than 100 mg / dL)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: 32

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who will analyze the data will not know which group is 30 degrees and which group is 34 degrees.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services, hezar jarib Ave

City

isfahan

Province

Isfahan

Postal code
81746-73461

Approval date
2022-03-29, 1401/01/09

Ethics committee reference number
IR.MUI.MED.REC.1401.001

Health conditions studied

1

Description of health condition studied

Blood sugar status

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood sugar

Timepoint

Before cardiopulmonary bypass, patients begin to cool down and reach the target temperature of group 1 to 30 ° C and group 2 to 34 ° C, before the patient warms up

Method of measurement

Glucometer device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The temperature will be raised to 30 degrees. Patients' blood sugar once before cardiopulmonary bypass, then when the patients start to cool down and reach the target group temperature of 1 to 30 degrees Celsius, and finally before the patient warms up again. Blood will be measured and recorded and blood sugar values will be compared in two groups of 30 ° C and 34 ° C. Device used to measure blood sugar: glucometer. Number of times 16 times

Category

Prevention

2

Description

Intervention group: The temperature will be raised to 34 degrees. Patients' blood sugar once before cardiopulmonary bypass, then when the patients start to cool down and reach the target group temperature of 1 to 34 degrees Celsius, and finally before the patient warms up again. Blood will be measured and recorded and blood sugar values will be compared in two groups of 30 ° C and 34 ° C. Device used to measure blood sugar: glucometer. Number of times 16 times

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Chamran Martyr Heart Specialized Hospita
Full name of responsible person
Fatemeh Mohammadi Shahrestanaki
Street address
Isfahan - Bozorgmehr Square, third Mushtaq Street,
after the city bridge
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8166173414
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mohammadifatemeh63813@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Mohammadi Shahrestanaki
Street address
Hezar Jerib St., Isfahan University of Medical Sciences
and Health Services
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Phone
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Mohammadi Shahrestanaki
Position
perfusionist
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Mohammadi Shahrestanaki

Position

perfusionist

Latest degree

Master

Other areas of specialty/work

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Email

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable