Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the relationship between the duration of rewarming patients and the incidence of acute kidney injury after coronary artery bypass

Protocol summary

Study aim
Determining the relationship between the duration of rewarming patients and the incidence of acute kidney injury after coronary artery bypass surgery

Design
A randomized, single-blinding clinical trial, with the parallel groups, Phase 3 on 80 patients

Settings and conduct
In this randomized, single-blind clinical trial study, 80 eligible patients referred to Chamran Hospital in Isfahan will be enrolled in the study and randomly divided into two groups. Rewarming of patients in the first group will be done at a fast rapid and in the second group at a slow rapid. In this study, the interventionist is aware of the type of intervention in each group, but the patient, researcher, and statistical analyst will not be aware of the type of intervention. Then, the incidence of acute kidney injury and blood parameters of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria included patients who were candidates for elective coronary artery bypass grafting, aged 40 to 75 years, EF greater than 40%, and written consent to participate in the study. Exclusion criteria included the creatinine level greater than 1.4 mg/dl before surgery, candidate for multiple surgeries simultaneously, need emergency surgery, reoperation, history of angiography in the past 72 hours, history of stroke, history of any kidney disease.

Intervention groups
Intervention group: In this group the patient is rewarmed to a temperature of 37°C with a maximum gradient of 10°C between the nasopharyngeal temperature and the warm water (Fast rate group). Control group: In this group, the patient is rewarmed to a temperature of 37°C with a maximum gradient of 5°C between the nasopharyngeal temperature and the warm water (Slow rate group).

Main outcome variables
Acute kidney injury; Creatinine; Urine output; Glomerular Filtration Rate(GFR); Complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N83**
Registration date: **2025-08-16, 1404/05/25**
Registration timing: **prospective**

Last update: **2025-08-16, 1404/05/25**
Update count: **0**

Registration date
2025-08-16, 1404/05/25

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-21, 1404/06/30

Expected recruitment end date
2026-01-21, 1404/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the relationship between the duration of rewarming patients and the incidence of acute kidney injury after coronary artery bypass

Public title

Relationship between the duration of rewarming patients and the incidence of acute kidney injury after heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients eligible for elective coronary artery bypass grafting Age range 40 to 75 years EF greater than 40% Written consent to participate in the study

Exclusion criteria:

Having a creatinine level more than 1.4 mg/dl before surgery or EGFR < 60 ml/min/1.73 m2 Patients who are candidates for multiple surgeries at the same time (such as valve replacement and Coronary artery bypass) Patients who require emergency surgery Reoperation Having a history of angiography in the last 72 hours Having a history of stroke or any neurological disease Performing dialysis before surgery or chronic chronic kidney disease or a history of any kidney disease

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 80 eligible patients are randomly selected. For this, the letter A is written on 40 sheets, and the letter B is written on 40 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to comply with the blinding conditions, due to the difference in the intervention method in each group to adjust the speed of rewarming of the patient, the interventionist is aware of the type of intervention in each group. It should be noted that it has also been explained to the patient before including the study that one of the two rewarming methods will be performed for them by chance and they may be placed in one of the two groups and if they consent, they will be entered into the study. Therefore, the patient undergoes this process during surgery and therefore will not be aware of the type of intervention. Also, the person collecting the data and the statistician will not have any knowledge of the type of intervention in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2025-04-14, 1404/01/25

Ethics committee reference number

IR.MUI.MED.REC.1404.027

Health conditions studied

1

Description of health condition studied

Coronary artery bypass surgery

ICD-10 code

I25.810

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

Primary outcomes

1

Description

Creatinine

Timepoint

Before surgery, the first, second, third, and seventh days

after surgery

Method of measurement

Blood test

2

Description

Urine output

Timepoint

Before surgery, the first, second, third, and seventh days after surgery

Method of measurement

Volume of urine in the urine bag

3

Description

Glomerular Filtration Rate(GFR)

Timepoint

Before surgery, the first, second, third, and seventh days after surgery

Method of measurement

Based on formula: [175 × Serum Cr ^(-1.154)] × [age ^ (-0.203) × 1.212]

4

Description

Acute kidney injury

Timepoint

After surgery

Method of measurement

Based on the Kidney Disease: Improving Global Outcomes (KDIGO) criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients are cannulated in the ascending aorta and right atrium after systemic heparinization. Cardiopulmonary bypass is performed under mild hypothermia (30°C). Mean arterial pressure is maintained at 80-90 mmHg throughout the coronary artery bypass. After the last distal anastomosis, rewarming is performed to 37°C with a maximum gradient of 10°C between nasopharyngeal temperature and warm water (rapid rate group).

Category

Treatment - Surgery

2

Description

Control group: In this group, patients are cannulated in the ascending aorta and right atrium after systemic heparinization. Cardiopulmonary bypass is performed under mild hypothermia (30°C). Mean arterial pressure is maintained at 80-90 mmHg throughout the coronary artery bypass. After the last distal anastomosis, rewarming is performed to 37°C with a maximum gradient of 5°C between nasopharyngeal temperature and warm water (slow speed group).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Mahmood Saeidi

Street address

2nd Moshtagh Street, Isfahan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Vice Chancellor for Research, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Street

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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

Isfahan 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
Mahmoud Saeidi
Position
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Person responsible for updating data

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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 further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available