

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of acute normovolemic blood dilution on the function of vital organs in patients who are candidates for heart surgery

Protocol summary

Study aim

Determining the effect of acute normovolemic blood dilution on the function of vital organs in patients who are candidates for heart surgery

Design

A controlled, parallel-group, triple-blinded, randomized clinical trial on 60 patients. Randomized Block Design method was used for randomization.

Settings and conduct

In the intervention group, one unit of blood is taken from adult patients who are candidates for heart surgery with hemoglobin greater than or equal to 14 after general anesthesia. In the control group, there are patients who are candidates for heart surgery with hemoglobin greater than or equal to 14, and we only perform routine heart surgery interventions. The place of study will be Chamran Hospital, Isfahan. Patients, researchers and analysts are not aware of the patient group.

Participants/Inclusion and exclusion criteria

The participants of the study are adult patients who are candidates for heart surgery with hemoglobin greater than or equal to 14.

Intervention groups

In the intervention group, one unit of blood is taken from adult patients who are candidates for heart surgery with hemoglobin greater than or equal to 14 after general anesthesia. Blood sampling is done through an arterial catheter that is implanted for the purpose of invasive blood pressure measurement. In the control group, there are patients who are candidates for heart surgery with hemoglobin greater than or equal to 14, and we only perform routine heart surgery interventions.

Main outcome variables

Renal function and respiratory function of the patient 48 hours after the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230508058118N1**

Registration date: **2023-11-05, 1402/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-05, 1402/08/14**

Update count: **0**

Registration date

2023-11-05, 1402/08/14

Registrant information

Name

Amirreza Mojganian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3521 3457

Email address

amirreza75mojganian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-05, 1402/08/14

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of acute normovolemic blood dilution on the function of vital organs in patients who are candidates for heart surgery

Public title

Investigating the effect of acute normovolemic blood dilution on the function of vital organs in patients who are candidates for heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients candidates for heart surgery Ejection fraction more than 40% Hemoglobin greater than and equal to 14 No kidney, liver, respiratory or brain failure

Exclusion criteria:

Pump time more than 120 minutes Use of circulatory arrest Reoperation due to surgical bleeding

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

This stage will be by randomized block design method. At this stage, patients will be divided into 2 blocks (30 blocks of 2). Then they are sorted according to the national code (the larger national code of the first row of the block and the smaller national code of the second row of the block). After that, we refer to the table of random numbers for each block. If the selected number was from 0 to 4, the patient in the first row will join group A and the patient in the second row will join group B. If the selected number is from 5 to 9, the patient in the first row will join group B and the patient in the second row will join group A. After 30 patients of group A and 30 patients of group B were determined, group A will be the intervention group and group B will be the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient, all study investigators and data analyzers were blinded to patient grouping. The patient is unconscious during the intervention, and the study researchers (data collectors) and data analyzers are unaware of the intervention.

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

Vice Chancellor for Research and Technology, Hezar Jerib St. Isfahan University of Medical Sciences and Health Services, Building No. 4

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-11-10, 1401/08/19

Ethics committee reference number

IR.MUI.MED.REC.1401.288

Health conditions studied

1

Description of health condition studied

Coronary artery bypass surgery

ICD-10 code

I97.190

ICD-10 code description

Other postprocedural cardiac functional disturbances following cardiac surgery

Primary outcomes

1

Description

Postoperative renal function

Timepoint

24 and 48 hours after the operation

Method of measurement

Creatinine and blood urea nitrogen test

2

Description

Postoperative pulmonary function

Timepoint

24 and 48 hours after the operation

Method of measurement

Venous blood gas test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Storing the blood of patients before the operation and injecting it after the operation

Category

Rehabilitation

2

Description

Control group: Routine open heart surgery

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital, Isfahan

Full name of responsible person

Seyyed Alireza Hosseini

Street address

Chamran Hospital, After Shahristan Bridge, Salman Farsi St

City

Isfahan

Province

Isfahan

Postal code

8158388997

Phone

+98 31 3260 0961

Email

education@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Vice Chancellor for Research and Technology, Hezar Jerib St. Esfahan University of Medical Sciences and Health Services, Building No. 4

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

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

Amirreza Mozhgani

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Alzahra Hospital, Sofeh Blvd.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

amirreza75mojganian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amirreza Mozhgani

Position

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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Amirreza Mozhgani
Position
Intern
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General Practitioner
Street address
Alzahra Hospital, Sofeh Blvd.
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Email
amirreza75mojganian@gmail.com

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

Information is kept confidential.

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

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

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

After publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Isfahan University of Medical Sciences, Amirreza Mozhgani

What processes are involved for a request to access data/document

By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided.

Comments