

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the use of the cardioplegic material through the descending and ascending aorta in the simultaneous removal of the heart and liver in organ donation: a randomized controlled clinical trial phase II

Protocol summary

Study aim

Comparison of the effect of using cardioplegic substances through the descending and ascending aorta in the simultaneous removal of the heart and liver on the effectiveness of the transplant and the amount of cardioplegic substance used.

Design

The potential 54 organ donors are dividing in two groups consisting of control and main groups with randomization by sealed envelope. This study is a double-blind clinical trial and only the operating surgeon of the study has the complete information of each patient. The rest of the medical team performing before and after surgery observations are not aware of patients' study group.

Settings and conduct

This is a phase II randomized controlled clinical trial, aiming to compare the use of the cardioplegic material through the descending and ascending aorta in the simultaneous removal of the heart and liver in organ donation. Only the operating surgeon of the study has the complete information of each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Eligible for organ donation and have consent and aware of the donation
Exclusion criteria: Liver cirrhosis, heart failure, and prior heart surgery

Intervention groups

In the control group, we using the classic strategy of cardioplegic solution infusion in the root of the aorta. In the main group, we use the new method that consists of sternotomy, complete isolation of aortic arch arteries, the clamp of ascending aorta, and injection of solution to descending aorta.

Main outcome variables

The cardiac ejection fraction, right after surgery, 2 weeks, 1 month, 3 months, 6 months, and 1 year after the operation
The volume of the cardioplegic solution used in the surgeries
The duration of the surgeries

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220919055992N1**

Registration date: **2022-11-03, 1401/08/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-03, 1401/08/12**

Update count: **0**

Registration date

2022-11-03, 1401/08/12

Registrant information

Name

Mohammadhosein Akhlaghpasand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 919 844 5400

Email address

akhlaghpasandm@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-21, 1401/07/29

Expected recruitment end date

2022-12-20, 1401/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the use of the cardioplegic material through the descending and ascending aorta in the simultaneous removal of the heart and liver in organ donation: a randomized controlled clinical trial phase II

Public title

Comparison of the use of the cardioplegic material through the descending and ascending aorta in organ donation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

eligible for organ donation have consent and aware of donation

Exclusion criteria:

liver cirrhosis heart failure prior heart surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the patients will be randomized by sealed envelope before the intervention

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial and only the operating surgeon of the study has the complete information of each patient. The rest of the medical team performing before and after surgery observations are not aware of patients' study group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Researches of the Iran university of medical sciences of Sciences

Street address

Hemat Highway, next to Milad Tower, Iran University of Medical Sciences, Central Headquarters Building, Research and Technology Vice-Chancellor

City

Tehran

Province

Tehran

Postal code

1988834567

Approval date

2021-01-21, 1399/11/02

Ethics committee reference number

IR.IUMS.REC.1399.1179

Health conditions studied

1

Description of health condition studied

Donors of organs and tissues

ICD-10 code

Z52

ICD-10 code description

Donors of organs and tissues

Primary outcomes

1

Description

The cardiac ejection fraction

Timepoint

right after surgery, 2 weeks, 1 month, 3 months, 6 months, and 1 year after the operation

Method of measurement

echocardiography

2

Description

The volume of the cardioplegic solution used in the surgery

Timepoint

at the operation

Method of measurement

fluid receiver

3

Description

The duration of the surgery

Timepoint

at the operation

Method of measurement

chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group contains organ donors who undergo an injection of a cardioplegic solution to descending aorta. Firstly sternotomy, complete isolation of aortic arch arteries, and simultaneous ligation of azygus and superior vena cava will be done then abdominal aorta cannulation after preparation of abdomen, clamp of ascending aorta and opening of inferior pulmonary vein and inferior vena cava will be performed. Finally we remove the heart and liver.

Category

Treatment - Surgery

2

Description

control group: Organ donors who undergo injection of a cardioplegic solution to ascending aorta

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Medical Research Training Center

Full name of responsible person

Sam Zeraatian Nejad Davani

Street address

Hazrat Rasool Akram Hospital, Niayesh St, Sattar Khan St,.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Kiwani

Street address

5th floor of the central headquarters, Iran University of Medical Sciences, next to Milad Tower, Hemat Highway.

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Phone

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research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadhosein Akhlaghpasand

Position

Associated researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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assistant professor

Latest degree

Subspecialist

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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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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