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 IIrandomized 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, 1month, 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)

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+98 919 844 5400

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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
chornometer

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Associated researcher
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Person responsible for updating data

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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