

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Safety and Feasibility Study of Using Hemoperfusion with HA380 Filter to Improve Heart and Liver Transplant Outcomes: Phase I Clinical Trial

Protocol summary

Study aim

Safety and Feasibility Assessment of Using Hemoperfusion with HA380 Filter to Improve Heart and Liver Transplant Outcomes

Design

A single arm phase I trial with a sample size of 5, based on 5 patients in the intervention group (will undergo hemoperfusion before organ procurement)

Settings and conduct

This single arm phase I trial with a sample size of 5 will conduct in Hazrat Rasool Akram Medical Research Training Center on 5 heart donors. This organ donors will undergo hemoperfusion, through the HA380 cartridge, before procure the heart for transplantation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: eligible for organ donation, have consent and aware of donation Exclusion criteria: liver cirrhosis, heart failure, prior heart surgery

Intervention groups

Intervention group: This group includes organ donors who will undergo hemoperfusion through the HA380 cartridge. First, sternotomy, complete separation of the aortic arch arteries and simultaneous ligation of the azygos and superior vena cava are performed, and after the preparation of the abdomen, abdominal aortic cannulation of the patients will be subjected to hemoperfusion through the HA380 cartridge. Finally, we procure the heart for donation.

Main outcome variables

Survival of heart recipient six months and one year after transplantation. Ejection fraction of heart recipient six months and one year after transplantation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220919055992N2**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **retrospective**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

Registration date

2023-06-18, 1402/03/28

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

2022-10-31, 1401/08/09

Expected recruitment end date

2022-11-05, 1401/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and Feasibility Study of Using Hemoperfusion with HA380 Filter to Improve Heart and Liver Transplant Outcomes: Phase I Clinical Trial

Public title

Using Hemoperfusion with HA380 Filter to Improve Heart

and Liver Transplant Outcomes

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 **80 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

2023-06-12, 1402/03/22

Ethics committee reference number

IR.IUMS.REC.1402.208

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

six months and one year after transplantation.

Method of measurement

month

2

Description

Survival of heart recipient.

Timepoint

six months and one year after transplantation.

Method of measurement

percent

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group includes organ donors who will undergo hemoperfusion through the HA380 cartridge. First, sternotomy, complete separation of the aortic arch arteries and simultaneous ligation of the azygos and superior vena cava are performed, and after the preparation of the abdomen, abdominal aortic cannulation of the patients will be subjected to hemoperfusion through the HA380 cartridge. Finally, we procure the heart for donation.

Category

Treatment - Other

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.,
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 1401
Email
Rasoolhospital@iums.ac.ir

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.
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2503
Email
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
Iran University of Medical Sciences
Full name of responsible person
Sam Zeraatian-Nejad Davani
Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Hazrat Rasool Akram Hospital, Niayesh St, Sattar
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

assistant professor

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Email

samzeraatian@yahoo.com

Person responsible for updating data

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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Shohada Tajrish Hospital, Tehran, 1988873554, Iran

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Postal code

1988873554

Phone

+98 919 844 5400

Fax**Email**

akhlaghpasandm@yahoo.com

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

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