

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Measurement of blood levels of D-dimer and CRP in brain dead patients and the effect of heparin with therapeutic dose on early renal and hepatic function of these organs in brain dead patients

Protocol summary

Study aim

Improving of kidney and liver transplant organ function in recipients from brain dead patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1-2 on 73 patients. Computer random table method was used for randomization

Settings and conduct

A double-blind clinical trial on 73 male and female patients with brain death who are candidates for organ donation at Sina Hospital in Tehran. The patients were randomly divided into two groups using a computerized random table method. The study is double-blind. Blinding process: The person who injected the drug does, the analyst, the outcome evaluator and the participant (double-blind) take place.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Brain dead patients aged 10-60 who are candidates for organ donation and have higher than normal CRP and D-dimer. Kidney failure patients undergoing dialysis on the transplant list and liver failure patients on the transplant list. Exclusion criteria: Exclusion criteria: Patients who are kidney or liver recipients for the second time. Brain death patients with Cr > 2.5mg/dl.

Intervention groups

Intervention group: 5000 units of intravenous heparin are injected every 6 hours from the beginning of the study. Control group: 5000 units of intravenous heparin are injected every 12 hours from the beginning of the study.

Main outcome variables

Measurement of the kidney and liver function organ in kidney and liver recipient patients from brain death patients who received heparin therapy or prophylaxis before organ donation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N16**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

mohammadreza khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1220

Email address

khajavim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Measurement of blood levels of D-dimer and CRP in brain dead patients and the effect of heparin with therapeutic dose on early renal and hepatic function of these organs in brain dead patients

Public title

Heparin therapy in brain dead patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Brain death patients in the ages of 10 to 60 years Renal failure patients undergoing dialysis on the transplant list Liver failure patients on the transplant list Brain death patients with D-dimer more than 500ng/ml Brain death patients with CRP greater than 20mg/L

Exclusion criteria:

Brain death patients who have $Cr \geq 2.5$ mg/dl. Renal failure patients who did not have a history of previous successful transplantation Liver failure patients who did not have a history of previous successful transplantation

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

For the randomization of patients who meet the inclusion criteria, the method of four blocks including intervention and control groups will be used. The preparation of randomization sequences will be done using the Random Generator software and the created sequences will be given to a trained staff member of the intensive care of unit who is not a member of the research group. The researchers of this study will not be aware of the existing sequences and arrangement of the blocks. After the patient enters the operating room, the trained person removes the first sequence from the special box of this study and according to the predetermined protocol, if it is H, it will be transferred to the intervention group, and if it is C, it will be transferred to the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients do not know their group. Eligible participants to receive heparin therapy (group H) or prophylactic heparin (group C) are determined according to a computerized randomization program. These drugs are prepared in syringes and the same volume and are

identified with the patient's name and hospital registration number, and in the special care department, these drugs are given to the nurse caring for the patient who is blind to the assigned groups for injection. Another investigator, who is blinded to the assigned groups, will evaluate the status of transplant success in kidney and liver recipients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Sina Hospital

Street address

Sina Hospital, Imam Khomeini st.

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2020-11-01, 1399/08/11

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1399.064

Health conditions studied**1****Description of health condition studied**

Brain dead

ICD-10 code

G96.8

ICD-10 code description

Other specified disorders of central nervous system

2**Description of health condition studied**

Thrombophilia

ICD-10 code

D68.69

ICD-10 code description

Other thrombophilia

Primary outcomes**1****Description**

Serum urea and creatinine of kidney transplant recipients

Timepoint

At the beginning of the patient's entry into the study and then daily until 7 days after transplantation

Method of measurement

By sending patients' blood samples to the laboratory

2

Description

Measurement of liver enzymes and bilirubin in liver transplant recipients

Timepoint

At the beginning of the patient's entry into the study and then daily until 7 days after transplantation

Method of measurement

By sending patients' blood samples to the laboratory

3

Description

Measurement of D-dimer in brain death patients

Timepoint

Once and 24 hours before organ donation

Method of measurement

By sending patients' blood samples to the laboratory

4

Description

Measurement of CRP in the blood of brain dead patients

Timepoint

Once and 24 hours before organ donation

Method of measurement

By sending patients' blood samples to the laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the confirmation of brain death of the patients and their family's consent to organ donation, first blood samples were measured to check CRP and D-dimer and 5000 units of heparin (manufactured by Caspian Tamin Company) with the help of the special care nurse according to the patient grouping. prepared and injected intravenously every 6 hours until the moment of organ donation and routine care to maintain the patient's hemodynamics continues until the moment of organ donation

Category

Treatment - Drugs

2

Description

Control group: After the confirmation of brain death of

the patients and their family's consent to organ donation, first blood samples were measured to check CRP and D-dimer and 5000 units of heparin (manufactured by Caspian Tamin Company) with the help of the special care nurse according to the patient grouping. prepared and injected intravenously every 12 hours until the moment of organ donation and routine care to maintain the patient's hemodynamics continues until the moment of organ donation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Mohammadreza Khajavi

Street address

Sina Hospital, Imam Khomeini st.

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khajavim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

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1417653761

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

Anesthesiologist

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Main study outcome data

When the data will become available and for how**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sina Hospital, Hasan Abad Sq, Imam Khomeni St

City

Tehran

long

Six months after the end of the study

To whom data/document is available

University researchers

Under which criteria data/document could be used

Share experiences to increase the knowledge

From where data/document is obtainable

khajavim@tums.ac.ir -Dr.khajavi

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

The request will be made by email and the answer will be given within two months

Comments