Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 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 thrapy 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≥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 Hospita
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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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
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Person responsible for updating data

Contact
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Position
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Other areas of specialty/work
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Email
khajavim@tums.ac.ir
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

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