Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of using the blood of a brain dead liver donor patient during liver transplantation on a liver recipient patient at Abu Ali Sina organ transplant center in 2023

Protocol summary

Study aim

Determining and comparing the amount of bleeding during and after liver transplant , the amount of blood injected during liver transplant surgery and after surgery, the rate of hepatic artery thrombosis after liver transplant, the rate of portal vein thrombosis, the rate of mortality during liver transplant surgery and after surgery., the rate of a primary dysfunction of the transplanted liver in each group and between the two groups

Design

The clinical trial, two parallel groups, phase 3, use of 4 block method with randomization software, double-blind, sample size 124

Settings and conduct

Shiraz, Iran double-blind. The person who receives the organ and the person who collects the information during and after the operation does not know the type of injected product.

Participants/Inclusion and exclusion criteria

Stability in vital signs Not receiving a high dose of an inotrope, Hemoglobulin level above 11, Age 18 to 40 years, Having the same blood group between the donor and the RH receptor Matching crossmatch, Transplantation from a brain-dead donor, Liver transplant for the first time ; blood transfusions other than blood collected from brain-dead patients Insufficient blood collected Bleeding more than 2000 cc in transplant surgery

Intervention groups

intervention group, patients whose blood will inject into them during and after liver transplantation from blood taken from a brain-dead patient.control group, patients whose blood was injected during and after liver transplantation from a random donor

Main outcome variables

1. Bleeding during and after liver TX in blood recipient group from brain death 2. Bleeding rate during and after liver TX in blood recipient group from random donor 3.amount of blood injected during the liver transplant in blood recipient group from brain death 4:amount of blood injected during the liver transplant in random donor blood recipient group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211008052699N2**
Registration date: **2023-07-23, 1402/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-23, 1402/05/01**
Update count: **0**

Registration date

2023-07-23, 1402/05/01

Registrant information

Name

Mohammad Eslamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

mr.esl67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using the blood of a brain dead liver donor patient during liver transplantation on a liver recipient patient at Abu Ali Sina organ transplant center in 2023

Public title

Investigating the effect of using the blood of a brain dead liver donor patient during liver transplantation on the liver recipient patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Stability in vital signs (heart rate less than 100 R/M, systolic pressure more than 100 mmHg). Hemoglobin level above 11 Age 18 to 40 years having blood group and RH between the donor and the recipient The same immunological conditions between donor and recipient in terms of cytomegaloviruses Matching based on sender and receiver cross match Transplantation from a brain dead donor Whole liver transplant Stability of vital signs at the time of liver transplant surgery Failure to receive inotrope before the transplant procedure No grade 3 or 4 encephalopathy before transplantation Age between 18 and 40 years Absence of evidence of portal vein thrombosis in preoperative examinations Liver transplant for the first time Not having a history of hepatic vein thrombosis (Bodekiari syndrome) or other diseases with high blood coagulation potential.

Exclusion criteria:

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups using computer randomization. This randomization of patients will be done by an independent computer programmer using the www.randomization.com database.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. The person who receives the organ and the person who collects the information during and after the operation does not know the type of injected product. The information during the operation is based on list number one and the information after the operation is based on the checklist. Number 2 is recorded by a trained anesthesiologist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

ZAND.Ave

City

SHIRAZ

Province

Fars

Postal code

8153683681

Approval date

2023-03-19, 1401/12/28

Ethics committee reference number

IR.SUMS.REC.1401.543

Health conditions studied

1

Description of health condition studied

LIVER TRANSPLANT

ICD-10 code

Y83.0

ICD-10 code description

Surgical operation with transplant of whole organ as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Bleeding rate during liver transplant surgery and after surgery (first 24 hours)

Timepoint

During the operation and up to 24 hours after the

operation

Method of measurement

Questionnaire

2

Description

The amount of blood injected during the liver transplant operation and after the operation (first 24 hours)

Timepoint

During the operation and up to 24 hours after the operation

Method of measurement

Questionnaire

3

Description

The rate of hepatic artery thrombosis during liver transplantation and after the operation (the first two weeks after transplantation)

Timepoint

During the transplant operation up to two weeks after the transplant

Method of measurement

Doppler ultrasound, CT abdominal angiography

4

Description

Mortality rate during liver transplant surgery and after surgery (first 30 days after transplant)

Timepoint

The first 30 days after liver transplantation

Method of measurement

questionnaire

5

Description

The degree of initial dysfunction of the transplanted liver (during the first week). Number of days of hospitalization in ICU after transplantation

Timepoint

The first week after transplantation

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: blood transfusion from a brain dead donor to a patient undergoing liver transplantation.The outcome of patients after transplantation is checked and recorded based on the checklist

Category

Treatment - Drugs

2

Description

Control group: Control group: blood transfusion from a non-brain-dead donor (from the blood bank) to a patient undergoing liver transplantation. In this group, based on the need for blood transfusion during the operation, blood is provided and injected from the blood bank. The outcome of the patients after transplantation is based on The checklist is checked and recorded

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

abu ali sina transplant center

Full name of responsible person

alireza shamsaefar

Street address

sadra.st

City

shiraz

Province

Fars

Postal code

8153683681

Phone

+98 71 3448 0000

Email

eslamian67@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Street address

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shiraz

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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

Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
alireza shamsaefar

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for scientific inquiries

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alireza shamsaefar

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data related to the main outcome information can be shared

When the data will become available and for how long
Access to data starts 4 months after the publication of the article

To whom data/document is available
Information release will be for academic researchers only

Under which criteria data/document could be used
The information can only be used for reporting in scientific congresses

From where data/document is obtainable
To obtain information, send a request to Shiraz Organ Transplantation Hospital or the following email eslamina67@yahoo.com

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

After the request is sent by email, it will be reviewed by the research committee of the center, and if the conditions are met, it will be sent within 2 months.

Comments