

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 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, Hemoglobin 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**

alireza shamsaefar

#### **Street address**

sadra

#### **City**

shiraz

#### **Province**

Fars

#### **Postal code**

8153683681

#### **Phone**

+98 71 3448 0000

#### **Email**

eslamian67@yahoo.com

### **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  
**Street address**  
sadra  
**City**  
shiraz  
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## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
alireza shamsaefar  
**Position**  
Associate professor  
**Latest degree**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
alireza shamsaefar  
**Position**  
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**Email**  
eslamina67@yahoo.com

## 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**