

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### continuous versus rapid infusion of albumin on the clinical outcomes of pediatric undergoing liver transplantation, a randomized clinical trial.

#### Protocol summary

##### Study aim

continuous versus rapid infusion of albumin on the clinical outcomes of pediatric undergoing liver transplantation

##### Design

A double-blind clinical trial that includes 42 liver transplant candidates under the age of 18. Permutation blocking randomization method will be used to divide patients into two groups.

##### Settings and conduct

at Bou Ali Sina Organ Transplantation Hospital in Shiraz and need to receive albumin for at least 48 hours. Patients are divided into two groups of 21 people using a random number table of unclassified randomization and with a random ratio of 1:1. The first group received albumin at a dose of 0.5 to 1 g/kg slowly for 180 minutes and the second group received the same dose quickly for 30 minutes. Albumin injection is done up to 48 hours after transplantation and in at least 3 doses.

##### Participants/Inclusion and exclusion criteria

Including factors: All liver transplant candidates under 18 years old  
Excluding factors: re-transplantation  
Simultaneous liver and kidney transplantation  
Hemorrhagic shock after transplantation during hospitalization  
Known hypersensitivity to albumin

##### Intervention groups

Patients are randomly divided into two groups: the first group received albumin at a dose of 0.5 to 1 g/kg slowly for 180 minutes and the second group received the same dose quickly for 30 minutes. Albumin injection is done up to 48 hours after transplantation and at least in 3 doses.

##### Main outcome variables

1- Examination of 24-hour urine volume after liver transplantation  
2- Incidence and stability of abdominal ascites, pleural effusion and leakage rate after transplantation based on radiological findings  
3- Incidence of portal vein thrombosis and the amount of hepatic artery based on radiological findings  
4- Increase in albumin number after transplantation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120731010453N5**

Registration date: **2023-07-04, 1402/04/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-04, 1402/04/13**

Update count: **0**

##### Registration date

2023-07-04, 1402/04/13

##### Registrant information

##### Name

Mojtaba Shafiekhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3242 4255

##### Email address

mshafikhan@sums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2023-07-01, 1402/04/10

##### Expected recruitment end date

2023-12-06, 1402/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

continuous versus rapid infusion of albumin on the clinical outcomes of pediatric undergoing liver transplantation, a randomized clinical trial.

#### Public title

continuous versus rapid infusion of albumin on the clinical outcomes of pediatric undergoing liver transplantation

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

11 patients which candidate to liver transplant younger than 18 years old

##### Exclusion criteria:

Re-transplantation simultaneous liver and kidney transplantation Hemorrhagic shock after liver transplantation during hospitalization known Hypersensitivity to albumin

#### Age

To 18 years old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: 42

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

After liver transplant surgery, all eligible patients are divided into two groups of 21 people, intervention and control, using a random number table, permutation blocking method. This table was prepared by a biostatistician and the patients are divided into one of two groups receiving fast and slow albumin according to the order of sampling according to the table.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The albumin prescription will be given by the gastroenterologist or pediatric special care specialist, and the head of the department, who does not have a role in the evaluation of results and data analysis, will assign the patients to It divides the above two groups, so the prescribing person as well as the researchers of this study are blinded in terms of what albumin regimen the patient receives.

#### 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

Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

###### City

shiraz

###### Province

Fars

###### Postal code

71348-14336

##### Approval date

2023-05-30, 1402/03/09

##### Ethics committee reference number

IR.SUMS.REC.1402.098

### Health conditions studied

#### 1

##### Description of health condition studied

liver transplantation

##### ICD-10 code

T86.49

##### ICD-10 code description

Other complications of liver transplant

### Primary outcomes

#### 1

##### Description

Albumin level after transplantation

##### Timepoint

during hospitalization

##### Method of measurement

By measuring plasma level of albumin

#### 2

##### Description

24-hour urine volume

##### Timepoint

During hospitalization

##### Method of measurement

By reviewing patient information

### Secondary outcomes

#### 1

##### Description

Required dose of intravenous or oral diuretic after transplantation

##### Timepoint

during hospitalization  
**Method of measurement**  
Based on the drug chart

## 2

**Description**  
The required dose of inotropes and vasopressors after liver transplantation  
**Timepoint**  
during hospitalization  
**Method of measurement**  
Based on the drug chart

## 3

**Description**  
Hospital and ICU stay  
**Timepoint**  
During hospital and ICU stay  
**Method of measurement**  
By reviewing patient information

## 4

**Description**  
Duration of ventilation  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 5

**Description**  
Hemodynamic status and patient resuscitation after shock  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 6

**Description**  
Status of transplanted liver  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 7

**Description**  
Death rate  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 8

**Description**  
Incidence of post-transplant infections

**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 9

**Description**  
The incidence and stability of abdominal ascites  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 10

**Description**  
Pleural effusion  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 11

**Description**  
Incidence of portal vein thrombosis  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## 12

**Description**  
Leakage rate after transplant  
**Timepoint**  
during hospitalization  
**Method of measurement**  
By reviewing patient information

## **Intervention groups**

### 1

**Description**  
Intervention group: They receive albumin at a dose of 0.5 to 1 g/kg slowly over 180 minutes.  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: They receive albumin at a dose of 0.5 to 1 g/kg rapidly for 30 minutes  
**Category**  
Treatment - Drugs

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Abu Ali Sina Organ Transplant hospital

**Full name of responsible person**

Mojtaba Shafiekhani

**Street address**

Abu Ali Sina Organ Transplant, Sadra Highway

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shiraz

**Province**

Fars

**Postal code**

71994-67985

**Phone**

+98 71 3344 0000

**Email**

mojtabashafiekhani@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

mohammad mehdi hashempour

**Street address**

Central building of Shiraz University of Medical Sciences Zand St

**City**

shiraz

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relation@sums.ac.ir

**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**

Mojtaba Shafiekhani

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Pharmacy, Karafrin street, Roknabad, Shiraz

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Other areas of specialty/work**

clinical pharmacy

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### Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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assistant professor

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**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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available