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:
ll 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

City
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

Province
Fars

Postal code
71348-14336

Phone
+98 71 3212 2713

Email
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

City
Shiraz

Province
Fars

Postal code
71546-57145

Phone
+98 71 3242 4255

Fax
+98 71 1242 4126

Email
mojtabashafiekhani@gmail.com

Person responsible for scientific 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
clinical pharmacy

Street address
دانشکده داروسازی شیراز, رکن آباد , خیابان کارآفرین

City
shiraz

Province
Fars

Postal code
71546-57145

Phone
+98 71 3242 4255

Email
mshafikhan@sums.ac.ir

Person responsible for updating data

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
clinical pharmacy
Street address
School of Pharmacy, Karafrin street, Roknabad, Shiraz
City
Shiraz
Province
Fars
Postal code
71546-57145
Phone
+98 71 3242 4255
Fax
+98 71 1242 4126
Email
mshafikhan@sums.ac.ir

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