

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of albumin-normal saline and albumin-gelatin injection on early outcome after liver transplant surgery

Protocol summary

Study aim

Comparison of albumin-normal saline and albumin-gelatin injection on early outcome after liver transplant surgery

Design

A randomized controlled clinical trial with 100 randomized double-blind, placebo-controlled trials will be performed. Simple randomization will be done using a random table.

Settings and conduct

This study will conduct to evaluate the prevalence of acute post-operative kidney injury in albumin-normal saline and albumin-gelatin patients in liver transplant surgery in Bo Ali Sina Hospital, Shiraz. Induction and maintenance of anesthesia and all necessary actions in the operating room are performed by an anesthesiologist who is not a project associate, and the researcher who is responsible for recording and tracking patients in the transplant intensive care unit is unaware of the technique used during surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The final stage of liver disease, Age over 18 years, Patients candidate for liver transplantation from brain death donors. Exclusion criteria: Liver recipients from live donors, Patients undergoing redo transplantation, History of upper abdominal surgery, A history of allergies to colloids, History of kidney dysfunction confirmed by laboratory and ultrasound sonography.

Intervention groups

In group 1, 10 grams of albumin in 1000 cc normal saline is infused from the beginning to the end of the procedure. In group two, the main preservative fluid is gelatin, which is injected based on the hemodynamic and CVP parameters from the beginning of the clamping to the end of surgery, one liter of normal saline containing 10 g of albumin is infused too.

Main outcome variables

Glomerular filtration rate, Serum creatinine level, Blood

Urea Nitrogen, Liver Function Tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N88**

Registration date: **2019-09-17, 1398/06/26**

Registration timing: **prospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **0**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-21, 1398/06/30

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of albumin-normal saline and albumin-gelatin injection on early outcome after liver transplant surgery

Public title
Comparison of albumin-normal saline and albumin-gelatin injection on early outcome after liver transplant surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 The final stage of liver disease Age over 18 years
 Patients candidate for liver transplantation from brain death donors
Exclusion criteria:
 Liver recipients from live donors Patients undergoing redo transplantation History of upper abdominal surgery
 A history of allergies to colloids History of kidney dysfunction confirmed by laboratory and ultrasound tests

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided into two groups of albumin-normal saline and gelatin-albumin group based on simple randomization by using randomized quadruple blocks of randomization table which is derived from www.randomization.org.

Blinding (investigator's opinion)
Double blinded

Blinding description
Induction and maintenance of anesthesia and all necessary actions in the operating room are performed by an anesthesiologist who is not a project associate. And the researcher who is responsible for recording and tracking patients in the transplant intensive care unit is unaware of the technique used during surgery.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Shiraz University of Medical Sciences

Street address

Vice chancellor for research, 7th floor of central building of Shiraz University of medical sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-08-03, 1398/05/12

Ethics committee reference number

IR.SUMS.MED.REC.1398.323

Health conditions studied

1

Description of health condition studied

Liver transplant

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

Primary outcomes

1

Description

Glomerular filtration rate

Timepoint

On the first day, second day, third day, fifth day and the last day of hospitalization

Method of measurement

Cochcroft and Gault formula

2

Description

Serum creatinine level

Timepoint

On the first day, second day, third day, fifth day and the last day of hospitalization

Method of measurement

Venous blood sample

3

Description

Blood Urea Nitrogen

Timepoint

On the first day, second day, third day, fifth day and the last day of hospitalization

Method of measurement

Venous blood sample

4

Description

Liver Function Tests: (AST, ALT, ALKP, INR, Bilirubin), Albumin

Timepoint

On the first day, second day, third day, fifth day and the last day of hospitalization

Method of measurement

Venous blood sample

Secondary outcomes

1

Description

ICU stay

Timepoint

At arrival time until the discharge from intensive care unit

Method of measurement

Observation

2

Description

Time interval between completion of operation and extubation

Timepoint

Between completion of operation to extubation

Method of measurement

Observation

3

Description

Hospital Stay

Timepoint

Hospital discharge time

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: In group 1, 10 grams of albumin in 1000 cc normal saline is infused from the beginning to the end of the procedure.

Category

Prevention

2

Description

Intervention group: In group two, the main preservative fluid is gelatin, which is injected based on the hemodynamic and CVP parameters from the beginning of the clamping to the end of surgery, one liter of normal saline containing 10 g of albumin is infused too.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Bu Ali Sadra Hospital

Full name of responsible person

Samaneh Ghazanfar Tehran

Street address

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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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
Samaneh Ghazanfar Tehran
Position
Transplant Anesthesia Fellowship
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available