

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The protective Effect of taurine on Ischemia-reperfusion syndrom Following liver transplantation

Protocol summary

Study aim

Investigating the preventive effect of taurine on the incidence of reperfusion syndrome in liver transplant recipients

Design

A double-blind clinical trial that includes 100 liver transplant candidates. A permutation block randomization method will be used to divide patients into two groups.

Settings and conduct

In this study, randomization is done using a table of random numbers, and in a ratio of one to one to one of the groups, taurine 2 grams in one place half an hour before the start of surgery and another group placebo 2 grams of carboxymethyl cellulose half an hour before the start of surgery. It is given and all the information of the patients during and after the operation is recorded and analyzed after collection. This study will be conducted in Bouali Hospital affiliated to Shiraz University of Medical Sciences, Shiraz, Iran.

Participants/Inclusion and exclusion criteria

All adult patients over 18 years of age who undergo liver transplantation are admitted to the organ transplant hospital Bu Ali Sina Shiraz is located. Re-transplantation or simultaneous liver and kidney transplantation as well as known sensitivity to taurine are among the exclusion criteria. For all patients, the method of performing the plan, its advantages and disadvantages are explained before anesthesia, and if the patient agrees, he is included in the study.

Intervention groups

Patients are randomly divided into two groups: one group is given 2 grams of taurine half an hour before surgery, and the other group is given 2 grams of placebo (carboxymethyl cellulose) half an hour before surgery.

Main outcome variables

Main outcomes: information after liver transplantation including length of stay in ICU and hospital, need for dialysis or CRRT after liver transplantation, functional

status of the transplanted organ during hospitalization and also patient death.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120731010453N3**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

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

2023-03-25, 1402/01/05

Expected recruitment end date

2023-12-13, 1402/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The protective Effect of taurine on Ischemia-reperfusion syndrom Following liver transplantation

Public title

Preventive effect of taurine drug on liver transplant recipients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients which candidate to liver transplant older than 18 years old

Exclusion criteria:

Re-transplantation or simultaneous liver and kidney transplantation Hypersensitivity to taurine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients are randomly divided into two groups receiving taurine supplement or placebo according to the permuted block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, transplant surgeon; transplant anesthesiologist and clinical pharmacist are completely blind to the type of intervention.

Placebo

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

2023-02-08, 1401/11/19

Ethics committee reference number

IR.SUMS.REC.1401.659

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**

Occurrence of reperfusion syndrome during the surgery

Timepoint

During the surgery

Method of measurement

By reviewing patient information

2**Description**

The required dose of norepinephrine during surgery in order to correct the hypotension

Timepoint

During the surgery

Method of measurement

By reviewing patient information

Secondary outcomes**1****Description**

The functional state of the organ from the time of transplantation to the time of discharge

Timepoint

Duration of hospitalization

Method of measurement

By reviewing patient file information

2**Description**

Duration of hospitalization in the ICU hospital for CRRT or

dialysis
Timepoint
Duration of hospitalization
Method of measurement
By reviewing patient file information

3

Description
Mortality rate
Timepoint
Duration of hospitalization
Method of measurement
By reviewing patient file information

4

Description
Need for CRRT or dialysis during hospitalization
Timepoint
Duration of hospitalization
Method of measurement
By reviewing patient file information

Intervention groups

1

Description
Intervention group: One group is given 2 grams of taurine half an hour before surgery.
Category
Prevention

2

Description
Control group: Placebo 2 grams of carboxymethyl cellulose is given half an hour before surgery
Category
Placebo

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
Erlangen
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
Medical Pharmacy
Street address
School of Pharmacy, Karafrin street, Roknabad, Shiraz
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
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
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