

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 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)

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+98 71 3242 4255

Email address

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mojtaba Shafiekhani

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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