

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effect of taurine on graft function in post-liver transplant recipients, a double-blind clinical trial

Protocol summary

Study aim

Determination of the effect of taurine in improvement of liver function in patients receiving liver transplantation in Shiraz as a double-blinded clinical trial

Design

Randomized controlled clinical trial, parallel groups, double blind, phase 3, on 102 patients. For randomization, random number table was used.

Settings and conduct

In our study, participants and investigator don't know that each patient has received which of the taurine or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria before randomization: Age older than 18 years, hospitalization for at least 1 week and filling informed consent. Exclusion criteria before randomization: allergy to taurine, lack of consent, pregnancy and lactation, simultaneous liver and kidney transplantation, parenteral nutrition containing parenteral amino acids, heart failure and lithium.

Intervention groups

patients will be divided randomly into two groups of receiving: taurine (500 milligrams twice a day) or placebo (carboxy methyl cellulose) (500 milligrams twice a day) for 1 month.

Main outcome variables

Improvement of the transplanted liver function regarding hepatic enzymes; Prevention of acute rejection of the transplanted organ; Rate of new-onset diabetes after transplantation; Rate of delirium development.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200312046755N1**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **prospective**

Last update: **2020-07-18, 1399/04/28**

Update count: **0**

Registration date

2020-07-18, 1399/04/28

Registrant information

Name

Shaghayegh Mottaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3242 5374

Email address

motaghish@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of taurine on graft function in post-liver transplant recipients, a double-blind clinical trial

Public title

Effect of taurine in liver transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All the patients older than 18 who are candidates for liver transplantation in Abu-Ali Sina hospital of Shiraz Hospitalization for at least 1 week after liver transplantation in Abu-Ali Sina hospital of Shiraz Filling the inclusion consent form by the patient

Exclusion criteria:

Allergy to taurine Lack of consent Pregnancy and lactation Simultaneous liver and kidney transplantation Parenteral nutrition containing parenteral amino acids, Heart failure Lithium

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

After liver transplantation surgery, using random number table, all qualified patients were divided to the two groups of intervention and control. This table is provided by bio-statistics specialist and patients are divided into one of the two groups in order of sampling to receive taurine or placebo randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

In our study, participants (patients) and researcher don't know that each patient has received which of the taurine or placebo. Taurine and placebo, both are provided in 500-milligram capsules with the same shape, color and size and in the same packaging and just one of the co-workers, who doesn't have any role in evaluation of outcomes and analyzing the data, knows about division of patients based on random number table.

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

Zand ave., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.SUMS.REC.1399.349

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

Improvement of the transplanted liver function regarding hepatic enzymes

Timepoint

Within the first month after transplantation

Method of measurement

Via studying the patient's file's data

2

Description

Prevention of acute rejection of the transplanted organ

Timepoint

Within the first month after transplantation

Method of measurement

Diagnosis and confirmation by the related physician

Secondary outcomes

1

Description

Rate of new-onset diabetes after transplantation

Timepoint

Within the first month after transplantation

Method of measurement

Laboratory data related to serum glucose and HbA1C

2

Description

Rate of delirium development

Timepoint

Within the first month after transplantation

Method of measurement

CAM-ICU score

Intervention groups

1

Description

Intervention group: Patients will receive taurine (from Purebulk Inc.) in amount of two 500-milligram capsules twice a day (equal to 2 grams per day) for 30 days.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive carboxy methyl cellulose (from Merck company) as placebo in amount of two 500-milligram capsules twice a day (equal to 2 grams per day) for 30 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu-Ali-Sina organ transplantation hospital

Full name of responsible person

Shaghayegh Mottaghi

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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

Shaghayegh Mottaghi

Position

Resident

Latest degree

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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