

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Impact of Octreotide on Renal Function of Patients after Liver Transplantation; A Randomized, Double-Blind, Placebo-Controlled Trial

Protocol summary

Study aim

The aim of this study is to evaluate the treatment with octreotide for 3 days in patients after Liver Transplantation. 60 patients will be enrolled and followed during 4 weeks. The effects on renal function will be evaluated 4 weeks after the beginning of the treatment by isotopic evidence and biochemist determinations.

Design

A Randomized, Double-Blind, Placebo-Controlled Trial

Settings and conduct

A Randomized, Double-Blind, Placebo-Controlled Trial

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Age between 18 and 60 years • Cirrhosis of the liver defined by clinical, biochemical or histological • That, properly informed, give their consent to participate in the study and undergo tests and examinations that entails • Women of childbearing potential: pregnancy test negative serum or urine, and acceptance of use of adequate contraception since at least 14 days prior to the first dose of study drug until 14 days after the last dose Exclusion Criteria: • Pregnant women, nursing mothers, or those who intend to become pregnant during the study period • Systolic blood pressure ≥ 150 mmHg and / or diastolic blood pressure ≥ 90 mmHg • Previous treatment with transjugular intrahepatic portosystemic shunt (TIPS) or surgical portosystemic shunts

Intervention groups

Drug: Octreotide Octreotide by IV injection 50 mcg per hours for 3 days. Drug: Placebo placebo by IV injection 50 mcg per hours for 3 days.

Main outcome variables

1. Glomerular filtration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190619043942N1**

Registration date: **2021-12-09, 1400/09/18**

Registration timing: **retrospective**

Last update: **2021-12-09, 1400/09/18**

Update count: **0**

Registration date

2021-12-09, 1400/09/18

Registrant information

Name

Hoda Safa Isini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 9615

Email address

hodasafa225@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of Octreotide on Renal Function of Patients after Liver Transplantation; A Randomized, Double-Blind, Placebo-Controlled Trial

Public title

Impact of Octreotide on Renal Function of Patients after Liver Transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1.Age between 18 and 60 years 2.Cirrhosis of the liver defined by clinical, biochemical or histological That, properly informed, give their consent to participate in the study and undergo tests and examinations that entails Women of childbearing potential: pregnancy test negative serum or urine, and acceptance of use of adequate contraception since at least 14 days prior to the first dose of study drug until 14 days after the last dose

Exclusion criteria:

1.Pregnant women, nursing mothers, or those who intend to become pregnant during the study period 2.Systolic blood pressure ≥ 150 mmHg and / or diastolic blood pressure ≥ 90 mmHg 3.Previous treatment with transjugular intrahepatic portosystemic shunt (TIPS) or surgical portosystemic shunts 4.Simultaneous Liver, Kidney Transplant 5.Cardiac or respiratory failure 6.Positive for human immunodeficiency virus 7.Urinary retention 8.Ischemic heart disease or peripheral vascular disease 9.Narrow Angle Glaucoma 10.Cerebrovascular occlusions 11.Aortic Aneurysm 12.Thyrotoxicosis 13.Pheochromocytoma 14.Diabetes Melitus 15.History of Hemodialysis prior to Liver Transplant 16.PreTransplant Cr more than 2.5mg/dl

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomized into two groups at a ratio of 1:1 using random allocation software (RAS)(M. 2004). The randomization codes remained concealed until all patients had completed their follow-up and the database had been verified and closed. There is no emergency case that required breaking the blind on randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Allocation concealment: Numbered drug containers, Blinding description: This study is double blind. Researcher and clinical care giver who complete questionnaire and patients are blind

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 street

City

shiraz

Province

Fars

Postal code

71345-1978

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.SUMS.MED.REC.1400.252

Health conditions studied

1

Description of health condition studied

Liver Transplantation

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

Primary outcomes

1

Description

1. Glomerular filtration

Timepoint

3 Days after Intervention, 1week after Intervention, 4 weeks after Intervention

Method of measurement

Change in glomerular filtration rate measured by isotopic tests

Secondary outcomes

1

Description

Changes in renal function

Timepoint

3days, 1 week, 4 weeks after cessation of treatment

Method of measurement

Lab test

Intervention groups**1****Description**

intervention group 1: octerotide 50 mg / h intravenous infusion for three days from one of the Domestic manufacturer factory that will be provided by Namazi Hospital Intervention

Category

Treatment - Drugs

2**Description**

Control group: Placebo 50 mg / h intravenous infusion for three days from one of the domestic manufacturer factory, the same as octerotide

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Abualisina Hospital

Full name of responsible person

Kamran Bagheri Lankarani

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71937-11351

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+98 71 3230 9615

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Vice Chancellor of Research Affairs of Shiraz University of Medical Sciences

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Postal code

71937-11351

Phone**Email**

lankaran@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

kamran bagheri lankarani

Position

Professor of internal medicine

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

hoda safa

Position

Gastroenterologist

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Subspecialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The file contains the results analysis

When the data will become available and for how long

Six months after the completion of the project

To whom data/document is available

ethics committee With the permission of the researchers

Under which criteria data/document could be used

In accordance with the informed consent form and the proposal approved Use of information can only be done anonymously For the purpose of verifying and approving the original proposal Only researchers related to this project will have access to information If approved by the Research Vice-President of the University and the Ethics Committee: The use of other people for other research purposes will be possible.

From where data/document is obtainable

responsible person of project email Dr. Kamran Bagheri Lankarani

What processes are involved for a request to access data/document

Ask official request from the Deputy of Research and Technology(SUMS).

Comments