Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Street address
zand street
City
shiraz
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Postal code
71937-11351
Phone
+98 71 3230 9615
Email
lankaran@sums.ac.ir

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
Street address
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shiraz
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Fars
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

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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
Shiraz University of Medical Sciences
Full name of responsible person
hoda safa
Position
Gastroenterologist
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology
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71937-11351
Phone
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Email
hodasafa225@gmail.com

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