Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of noradrenaline with the combination of octreotide and midodrine in the treatment of hepatorenal syndrome type 1

Protocol summary

Study aim
Comparison of the effectiveness of noradrenaline treatment against combined treatment of midodrine and octreotide in hepatorenal syndrome

Design
Clinical trial with control group, with parallel groups, double-blind, randomized by randomized block method

Settings and conduct
This study was designed in Sayad Hospital in Gorgan. In this double-blind study (patients and researchers), patients were randomized into two intervention groups (patients suspected of HRS on noradrenaline treatment with an initial dose of 1 mg per hour with continuous injection and then in order to achieve the minimum output urine output of at least 400 ml per 12 hours, gradually increasing to a maximum dose of 4 mg/hour) and the control group (receive midodrine orally with an initial dose of 7.5 mg three times a day, with a dose increase to a maximum of 12.5 mg three times a day) once daily, with subcutaneous octreotide: starting dose of 100 µg three times daily and up to 200 µg three times daily, both groups 20 to 40 g/day will receive albumin intravenously) are divided.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 70 years/ diagnosis of hepatorenal syndrome based on the revised diagnostic criteria of HRS, 2007: cirrhosis + ascites + increased serum creatinine level (more than 1.5 mg/dL) and failure to improve within 48 hours with diuretic discontinuation and Volume increase with albumin/no use of nephrotoxic drugs/no kidney parenchymal disease or obstructive uropathy in laboratory and ultrasound evaluation/Doubling of creatinine level to more than 2.5 mg/dL in 2 weeks or less/ Exclusion criteria: History of coronary disease and evidence of ventricular arrhythmia or cardiomyopathy

Intervention groups
Group 1/ midodrine, octreotide and albumin and group 2/ intervention group with noradrenaline and albumin treatment.

Main outcome variables
Treatment of hepatorenal syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230228057568N1**
Registration date: **2023-03-05, 1401/12/14**
Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**
Update count: **0**

Registration date
2023-03-05, 1401/12/14

Registrant information

Name
Maryam Maqsoudloo
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 17 3262 5346
Email address
maryamm.maqsoudl1367@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-21, 1402/01/01

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of noradrenaline with the combination of octreotide and midodrine in the treatment of hepatorenal syndrome type 1

Public title
Comparison of noradrenaline with the combination of octreotide and midodrine in the treatment of hepatorenal syndrome type 1
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis based on modified HRS diagnostic criteria in 2007: Cirrhosis with ascites and increased serum creatinine level (>1.5 mg/dL) with non-recovery up to 48 hours after diuretic discontinuation and volume increase with albumin Absence of shock Not receiving nephrotoxic drugs Absence of kidney parenchymal disease or obstructive uropathy in laboratory and ultrasound assessment Doubling of creatinine level to more than 2.5 mg/dL in 2 weeks or less
Exclusion criteria:
History of coronary disease and evidence of ventricular arrhythmia or cardiomyopathy obtained based on history taking, assessment of risk factors, physical examination, echocardiography and radiography.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: In order to randomize samples, we use a block method with quadrilateral blocks. In this way, one of the following blocks is first selected by accident (for example, with a dice), and according to the order in which those samples are We assign two groups (A for the group receiving Noradrenaline and B for the Standard treatment group). For example, if block 3 is selected and the first one is assigned to the group receiving the Noradrenaline, and the second and third samples will be allocated to the Standard treatment recipient group, the fourth will be assigned to the group receiving the Noradrenaline. Then for four samples, again, a block will be randomly selected. We will allocate it to it and this process will proceed to the end of the sampling.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind. In this way, all the patients and the student facilitator evaluating the designed interventions (internal medicine assistant, project manager) in the study or the outcomes after the project (internal medicine assistant and nephrology specialist) will not know about the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of medical sciences
Street address
Golestan University of Medical Sciences Research Office, The beginning of Shast Kolah Road, Hirkan Blvd, Basij Square
City
Gorgan
Province
Golestan
Postal code
4917761551
Approval date
2022-11-27, 1401/09/06
Ethics committee reference number
IR.GOUMS.REC.1401.374

Health conditions studied

1

Description of health condition studied
Hepatorenal Syndrome
ICD-10 code
K76.7
ICD-10 code description
Hepatorenal syndrome

Primary outcomes

1

Description
Reduction of serum creatinine level below 1.5 mg
Timepoint

Before the intervention and days 1, 3, 7 and 14

Method of measurement

Blood and urine samples

2

Description

Increase in 4-hour urine output above 200 ml

Timepoint

Before the intervention and days 1, 3, 7 and 14

Method of measurement

Blood and urine samples

3

Description

Statistically significant improvement in serum creatinine and sodium levels.

Timepoint

Before the intervention and days 1, 3, 7 and 14

Method of measurement

Blood and urine samples

Secondary outcomes

1

Description

Treatment of hepatorenal syndrome and mortality rate

Timepoint

Beginning and end of day 14

Method of measurement

Blood/urine samples and bedside examination

Intervention groups

1

Description

Intervention group: Patients receiving Noradrenaline and Albumin treatment/ In this group, patients with Hepatorenal Syndrome were treated with Noradrenaline at an initial dose of 1 mg/h with continuous injection and then gradually increased to a maximum dose of 4 mg/h in order to achieve a minimum urine output of at least 400 ml per 12 hours + Receiving Albumin on the first day of 1 gram per kilogram of body weight and then 20 to 40 grams per day intravenously for up to 14 days/ basic and clinical and laboratory information in both groups at the beginning and then on days 1, 3, 7, and 14 and the maximum time Readmission will be checked.

Category

Treatment - Drugs

2

Description

Control group: standard treatment of patients with Midodrine, Octreotide and albumin (receive Midodrine orally with an initial dose of 7.5 mg three times a day, with a dose increase up to a maximum of 12.5 mg three times a day, together with Octreotide subcutaneously: initial dose 100 µg three times a day and up to 200 µg three times a day +Receiving Albumin on the first day of 1 gram per kilogram of body weight and then 20 to 40 grams per day intravenously for up to 14 days / basic and clinical and laboratory information in both groups at the beginning and then on days 1, 3, 7, and 14 and the maximum time Readmission will be checked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayad Shirazi Hospital

Full name of responsible person

Dr. Saeed Amirkhanlou

Street address

Shahid Sayad Shirazi Hospital, Shahid Sayad Shirazi Boulevard, Bahnar Square, Gorgan

City

Gorgan

Province

Golestan

Postal code

49178677439

Phone

+98 17 3220 2154

Email

Sayyadlib@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Honarvar

Street address

Ethics Committee of the Vice Chancellor for Research and Technology, 3rd Floor, School of Dentistry, Golestan University of Medical Sciences, Shast Kola Road, Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

4934174523

Phone

+98 17 3245 0021

Email

tahghighat.g@goums.ac.ir

Grant name

Gorgan University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Maryam Maqsoudloo

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Number 11, Aseman building, Shahriar Alley 5, Shahriar Blvd, Shahryar town

City
Gorgan

Province
Golestan

Postal code
49178677439

Phone
+98 17 3262 5346

Fax

Email
maryamm.maqsoudl1367@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Dr. Saeed Amirkhanlou

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Nephrology's Clinic and Obstetrics and Gynecology Department, 2nd floor, Shahid Sayad Shirazi Hospital, Sayad Shirazi Blvd., Bahonar Square, Gorgan, Iran

City
Gorgan

Province
Golestan

Postal code
4915663158

Phone
+98 17 3226 1175

Email
drsam74ir@ymail.com

Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Maryam Maqsoudloo

Position
Resident

Latest degree
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Other areas of specialty/work
Internal Medicine

Street address
Number 11, Aseman building, Shahriar Alley 5, Shahriar Blvd, Shahryar town

City
Gorgan

Province
Golestan

Postal code
49178677439

Phone
+98 17 3262 5346

Fax

Email
maryamm.maqsoudl1367@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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no restrictions to perform statistical analyzes and access to data and documents. elated additional documents such as study protocol, data analysis program, etc. will also be shared.

From where data/document is obtainable

Dr. Maryam Maqsoodlou: internal resident/ phone number: 09113759570/ Email: maryamm.maqsoudl1367.com/ postal code: 4913983794/ address: Number 11, Aseman building, Shahriar Alley 5, Shahriar Blvd, Shahryar town, Gorgan city

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

The applicant should provide his / her study file and the purpose of receiving the data in the form of an email with his / her research file (research plan), then after 3 months the file will be provided to the person

Comments