Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Noradrenalin versus the combination of Midodrine and Octreotide in the treatment of patients with Hepatorenal syndrome type 1 and 2 referred to Alzahra Hospital since 2011 to 2012

Protocol summary

Summary

Objectives: To assess the efficacy of Noradrenalin in comparison with the efficacy of the combination of Midodrine and Octreotide in the treatment of patients with Hepatorenal syndrome (HPS) type 1 and 2 Design: A single-blinded randomized clinical trial on patients with HPS type 1 and 2 referred to Alzahra Hospital (affiliated to Isfahan University of Medical Sciences) since 2011 to 2012. Setting and conduct: Twenty two patients with HPS will divide into two groups randomly and will be treated with Noradrenalin or the combination of Midodrine and Octreotide. During the study, patients will be studied for renal and liver functions, continuous heart monitoring and urinary output measurement. Participants including major eligibility criteria: Inclusion criteria: HPS… Exclusion criteria: Improvement of renal function after volume expansion; history of infection, nephrotoxic drug usage or volume loss in recent week; contraindication to Noradrenalin, Midodrine or Octreotide; recent history of gastrointestinal bleeding; severe hepatic encephalopathy; hepatocellular carcinoma; platelet counts lower than 25000 per microliters; international normalized ratio (INR) more than 5; acute coronary syndrome Intervention: One group will be administered with the continuous infusion of Noradrenalin and the other group will be administered with the combination of oral Midodrine and intravenous infusion of Octreotide. Main outcome measures variable: Systolic, diastolic and mean atrial pressure; central vein pressure; heart rate; urinary output; serum and urinary sodium; glomerular filtration rate; serum and urinary creatinine; serum bilirubin; serum urea; plasma activated renin; plasma aldosterone

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107217085N1**
Registration date: **2011-11-22, 1390/09/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-11-22, 1390/09/01

Registrant information

Name

kambiz yazdanpanah

Name of organization / entity

Meical university of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 1669 4894

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Recruitment status

Recruitment complete

Funding source

Vice Chancellery for Reserch and Technology, Isfahan University of medical Sciences, Isfahan, Iran

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Noradrenalin versus the combination of Midodrine and Octreotide in the treatment of patients with Hepatorenal syndrome type 1 and 2 referred to Alzahra Hospital since 2011 to 2012

Public title
Noradrenalin versus Midodrin-Octerotid in Hepatorenal Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Hepatorenal syndrom patients ... Exclusion criteria: Improvement of renal function after volume expansion; history of infection, nephrotoxic drug usage or volume loss in recent week; contraindication to Noradrenalin, Midodrine or Octreotide; recent history of gastrointestinal bleeding; severe hepatic encephalopathy; hepatocellular carcinoma; platelet counts lower than 25000 per microliters; international normalized ratio (INR) more than 5; acute coronary syndrome
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee, Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran
City
Isfahan
Postal code
8174673461
Approval date
2011-08-01, 1390/05/10
Ethics committee reference number
390210

Health conditions studied

1

Description of health condition studied
Hepatorenal Syndrome type 1 & 2
ICD-10 code
K76.7
ICD-10 code description
Hepatorenal Syndrome

Primary outcomes

1

Description
Serum ceatinine
Timepoint
Before the study and every day during the study
Method of measurement
laboratory method

Secondary outcomes

1

Description
Systolic and diastolic pressure
Timepoint
Before the study and every 4 hours during the study
Method of measurement
sphygmomanometer

2

Description
Urinary output
Timepoint
Before the study and every day during the study
Method of measurement
Collecting scaled bag

3

Description
Serum and urinary sodium
Timepoint
Before the study and every day during the study
Method of measurement
Laboratory method

4

Description
Glomerular filtration rate
Timepoint

Before the study and every day during the study

Method of measurement

Cockroft-Gault formula

Intervention groups

1

Description

One group is treated with Noradrenalin infusion of 0.1 microgram per kilogram. The dose is escalated every 4 hours by 0.05 microgram per kilogram up to the maximum dose of 0.7 microgram per kilogram or until 10 millimeter increase in the mean arterial pressure. The drug is continued until creatinine is reached less than 1.5 milligram per deciliter or until 15 days.

Category

Treatment - Drugs

2

Description

The other group is treated with Octereotide infusion of 25 microgram per hour and oral Midodrin of 5 milligram three times a day up to the maximum dose of 45 milligram per day or until Mean arterial pressure is increased by 15 millimeter. The treatment is continued until creatinine is reached less than 1.5 milligram per deciliter or 15 days is elapsed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Kambiz Yazdanpanah

Street address

Al-Zahra Hospital, Isfahan University of Medical Sciences, Soffeh Street, Isfahan 81744, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery for Reserch and Technology, Isfahan University of Medical Sciences, Isfahan, Iran

Full name of responsible person

Peyman Adibi

Street address

Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

390210

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

Yes

Title of funding source

Vice Chancellery for Reserch and Technology, Isfahan University of Medical Sciences, Isfahan, Iran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Kambiz Yazdanpanah

Position

Fellowship of Gastroentrology and Hepatology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty