Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

PEG-Lactulose versus lactulose in the treatment of hepatic encephalopathy in cirrhotic patients in Shariati hospital.

Protocol summary

Summary

Our purpose is to assess the effect of Polyethylene Glycol (PEG) together with lactulose versus lactulose alone in the treatment of patients with hepatic encephalopathy. This mono-center trial will be performed in Shariati hospital, Tehran province, Iran and in 2, 24-patient groups and in a single-blind setting. Patients are randomly assigned to different treatment groups according to a block randomization number list. All patients with a known history of documented cirrhosis who had hepatic encephalopathy were eligible to participate in this trial regarding to inclusion criteria (age between 18 to 80, presence of cirrhosis and encephalopathy and sign of informed consent form) and exclusion criteria (acute liver failure, other causes of altered mental status, lack of agreement, hemodynamic instability and pregnancy). Lactulose group receive lactulose in a specific dose, orally or by enema. Polyethylene Glycol (PEG) – lactulose group, receive PEG solution additional to standard treatment that lactulose group received. Serial physical examinations will be performed by a team member; at beginning presentation and 24 hours later along with some clinical variables (CPT scoring system and MELD scoring system to assess severity of cirrhosis) and baseline laboratory test to assess the complete randomization between 2 groups. Along with physical examination, clinical variables and baseline laboratory tests, we'll also check the baseline and after-treatment level of blood level of ammonia as a probable severity indicator for hepatic encephalopathy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083117719N2**
Registration date: **2015-10-02, 1394/07/10**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-10-02, 1394/07/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Office for connection between industry, university and community, Tehran University of Medical Sciences

Expected recruitment start date

2015-09-10, 1394/06/19

Expected recruitment end date

2015-10-11, 1394/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

PEG-Lactulose versus lactulose in the treatment of hepatic encephalopathy in cirrhotic patients in Shariati hospital.

Public title

The effect of PEG in the treatment of hepatic encephalopathy

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age 18 to 80 years old; Documented cirrhosis with any underlying etiology; Any grade of hepatic encephalopathy; Signed informed consent by patient or his/her LARs (if there is an imperfect level of consciousness) Exclusion criteria: Acute liver failure that was defined as the onset of severe acute liver injury with encephalopathy and international normalized ratio (INR) of ≥1.5 in a patient without cirrhosis or preexisting liver disease; Altered mental status due to a diagnosis other than hepatic encephalopathy; Patient's or his/her LAR unwillingness to this trial; Hemodynamic instability which needs vasopressors for resuscitation; Pregnancy.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **48**
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
Tehran University of Medical Sciences, Shariati Hospital
Street address
Shariati Hospital, Ale Ahmad Exp.way, Tehran
City
Tehran
Postal code
Approval date
2015-03-01, 1393/12/10
Ethics committee reference number
416/984

Health conditions studied

1

Description of health condition studied
Cirrhosis
ICD-10 code
K74.6
ICD-10 code description
Other and unspecified cirrhosis of liver

Primary outcomes

1

Description
Severity of hepatic encephalopathy
Timepoint
At presentation and 24 h later
Method of measurement
HESA (Hepatic Encephalopathy Scoring Algorithm)

Secondary outcomes

1

Description
Blood level of ammonia
Timepoint
At presentation and 24 h later
Method of measurement
Blood sampling

Intervention groups

1

Description
Lactulose group (control group) will receive either 20 to 30 grams of lactulose (at least 3 doses in 24 hours) orally or by a nasogastric tube, or 200 grams of lactulose enema by a rectal tube for 24 hours.
Category
Treatment - Drugs

2

Description
Polyethylene Glycol (PEG) – lactulose group (intervention group), will receive a single dose of 4 liters of PEG solution contain PEG in an amount of 280 grams additional to standard treatment that lactulose group received (Lactulose group (control group) will receive either 20 to 30 grams of lactulose (at least 3 doses in 24 hours) orally or by a nasogastric tube, or 200 grams of lactulose enema by a rectal tube for 24 hours.).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital
Full name of responsible person
Dr Amir Ali Sohrabpour
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Shariati hospital, Ale Ahmad Exp Way, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences-Collaborative Office Between University,Industry and Society
Full name of responsible person
Ms Shamila Nazhati
Street address
Central Building of Tehran University of Medical Sciences, Ghods St. , Keshavarz Blvd. , Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences-Collaborative Office Between University,Industry and Society
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

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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