

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

Name

Amir Ali Sohrabpour

Name of organization / entity

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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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Web page address**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

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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****Contact****Name of organization / entity**

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Web page address**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