Terlipressin versus albumin in the prevention of paracentesis associated adverse events in patients with cirrhosis and tense ascites. A multicenter randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23876

Source
Nationaal Trial Register

Brief title
TAPP-study

Health condition

cirrhosis of the liver, ascites

Sponsors and support

Primary sponsor: Foundation for Liver Research (SLO)
Erasmus MC
c/o department of hepatology and gastroenterology,room Ca 326
Dr. Molewaterplein 40
3015 GD Rotterdam
tel (010) 463 5942
Source(s) of monetary or material Support: Dutch Society for Hepatology (NVH)
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Intervention

Outcome measures

Primary outcome

Decrease in EABV. This is an increase in plasma renin concentration (PRC) of more than 50% of baseline values 6 days after paracentesis.

Secondary outcome

1. Circulatory parameters;

2. Renal function;

3. Bodyweight (recurrence of ascites);

4. Adverse events;

5. Costs.

Study description

Background summary

Patients with cirrhosis and (tense) ascites requiring therapeutic paracentesis can be enrolled. They will be randomly assigned to receive either terlipressin or, the standard treatment, albumin iv for suppletion with paracentesis.

It will be studied whether terlipressin gives an equivalent prevention of decrease in effective arterial blood volume as albumin does in this setting.

Time points of this trial, when parameters will be taken, are at onset of paracentesis, 6 hours after, and 6 days after paracentesis. The safety follow-up will be for a duration of 2 months after which the patient can re-enter the study once. He or she will then automatically be placed in the other arm.

Study objective

The effect of terlipressin on the effective arterial blood volume (EABV) in patients with

cirrhosis and (tense) ascites who receive a therapeutic paracentesis, is equivalent to the current standard treatment with human albumin without the risks of a bloodproduct and with lower costs.

Study design

N/A

Intervention

Patients will be randomly assigned to receive either terlipressin or albumin, the standard treatment, iv when they receive a therapeutic paracentesis.
The terlipressin group will receive an iv-bolus of 1 mg terlipressin at onset of therapeutic paracentesis and another iv-bolus of 2 mg 6 hours after paracentesis.
The albumin group will receive 8 gr of albumin iv per liter of ascitic fluid removed.
At onset, after 6 hours, and on day 6 after paracentesis vital functions, blood, urine, and ascitic fluid samples will be taken to measure the effect of the medication.

Contacts

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Eligibility criteria

Inclusion criteria

1. Cirrhosis with tense ascites requiring therapeutic paracentesis;

2. Age 18-70;

3. Written informed consent.

Exclusion criteria

1. Hypertension treated with medication;

2. History of cardiac or coronary disease;

3. Circulatory unstable;

4. Until 5 days prior to paracentesis:

a. Infusion of a plasma expander;

b. Gastro-intestinal haemorrhage;

c. Spontaneous bacterial peritonitis;

5. Systemic administration of antibiotics within the past 14 days for a period of more than 24 hours, with the exception of quinolones;

6. Hepatocellular carcinoma;

7. Hepatic encephalopathy;

8. Pregnancy or lack of adequate contraception in sexually active females;

9. Any other condition which in the opinion of the investigator would make the patient unsuitable for enrolment, or could interfere with the patient participating in and completing the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2005
Enrollment:	84
Type:	Actual

Ethics review

Positive opinion

Date:	24-10-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL423
NTR-old	NTR463
Other	: N/A
ISRCTN	ISRCTN36383299

Study results

Summary results
N/A