

Terlipressin versus albumin in the prevention of paracentesis-associated adverse events in patients with cirrhosis and tense ascites

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/04/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR463

Study information

Scientific Title

Terlipressin versus albumin in the prevention of paracentesis associated adverse events in patients with cirrhosis and tense ascites: a multicentre randomised controlled trial

Acronym

TAPP-study

Study objectives

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 blood product and with lower costs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre randomised active-controlled parallel-group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cirrhosis of the liver/ascites

Interventions

Patients will be randomly assigned to receive either terlipressin or albumin, the standard treatment, intravenously (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 g of albumin iv per litre 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.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

1. Circulatory parameters
2. Renal function
3. Body weight (recurrence of ascites)
4. Adverse events
5. Costs

Completion date

30/11/2006

Eligibility**Key inclusion criteria**

1. Cirrhosis with tense ascites requiring therapeutic paracentesis
2. Aged 18 - 70 years
3. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Hypertension treated with medication
2. History of cardiac or coronary disease
3. Circulatory unstable
4. Until 5 days prior to paracentesis:
 - 4.1. Infusion of a plasma expander
 - 4.2. Gastro-intestinal haemorrhage
 - 4.3. 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

Date of first enrolment

01/12/2005

Date of final enrolment

30/11/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Centre

Rotterdam

Netherlands

3015 GD

Sponsor information

Organisation

Foundation for Liver and Gastrointestinal Research (SLO) (Netherlands)

ROR

<https://ror.org/04hzejq44>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Society for Hepatology (Nederlandse Vereniging voor Hepatologie [NVH]) (Netherlands)

Funder Name

Foundation for Liver and Gastrointestinal Research (SLO) (Netherlands) - Erasmus Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration