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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	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/04/2009	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Overall study start date
01/12/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
84

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)

Sponsor details
c/o Erasmus Medical Centre
Department of Hepatology and Gastroenterology
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Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration