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The natriuretic and diuretic effects of urodilatin in cirrhosis patients with severe sodium retention

Submission date 22/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/01/2007	**Overall study status** Completed	
Last Edited 14/01/2021	**Condition category** Digestive System	

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
N/A

Study information

Scientific Title
The natriuretic and diuretic effects of urodilatin in cirrhosis patients with severe sodium retention

Study objectives
Urodilatin is able to induce natriuresis and diuresis in liver cirrhosis patients with severe sodium retention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from local ethics committee (Den Videnskabsetiske Komité for Aarhus Amt), date of approval: 29 September 1998 (reference number: 1998/4274).

Study design
Randomised single-blind placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Decompensated liver cirrhosis.

Interventions
Comparison of 90 minutes intravenous (i.v.) infusion of synthetic urodilatin with placebo:
1. Urodilatin was dissolved in isotonic saline and the infusion dose was 20 ng/kg/min. Infusion rate was 0.27 mL/kg/hour
2. Placebo was isotonic saline

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Urodilatin

Primary outcome measure
The renal effects of Urodilatin were investigated in a clearance study. Primary outcomes were:
1. Urine flow rate
2. Urine sodium excretion rate
3. Plasma cyclic Guanosine 3',5'-MonoPhosphate (GMP)

Secondary outcome measures
1. Systemic blood pressure
2. The plasma hormones renin, angiotensin II and aldosterone

Overall study start date
28/01/1999

Completion date
01/02/2001

Eligibility

Key inclusion criteria
1. Presence of cirrhosis in a liver biopsy
2. Anamnestic, clinical and laboratory evidence of cirrhosis including ascites (verified by ultrasound), oesophagogastric varices (verified by gastroscopy), hypoalbuminemia and reduced prothrombin index
3. A 24 hour urine sodium excretion less than 60 mmol
4. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
15

Total final enrolment
7

Key exclusion criteria
1. Primary kidney disease (s-creatinine more than 200 mmol/L)
2. Congestive heart failure
3. Diabetes
4. Haemoglobin less than 6.0 mmol/L
5. A history of bladder dysfunction

Date of first enrolment
28/01/1999

Date of final enrolment
01/02/2001

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Medicine V
Aarhus
Denmark
8200

Sponsor information

Organisation
Aarhus University Hospital (Denmark)

Sponsor details
c/o Prof. Hendrik Vilstrup MD
Department of Medicine V
Aarhus
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DK-8200

Sponsor type
Hospital/treatment centre

Website
http://www.sundhed.dk/wps/portal/_s.155/1921?_ARTIKELGRUPPE_ID_=1044040715102806

ROR
https://ror.org/040r8fr65

Funder(s)

Funder type
Other

Funder Name
This is an investigator driven and funded trial.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2007	14/01/2021	Yes	No