

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

Submission date 22/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

<https://ror.org/040r8fr65>

Funder(s)

Funder type

Other

Funder Name

This is an investigator driven and funded trial.

Results and Publications

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