Urinary exosome expression of renal water and sodium transporters in compensated and decompensated liver or heart disease

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To investigate whether the expression of renal water and sodium transporters in urinary exosomes is different in compensated versus decompensated liver and heart disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32930

Source
ToetsingOnline

Brief title
Urinary exosomes

Condition

- Other condition
- Heart failures
- Hepatic and hepatobiliary disorders

Synonym
Congestive heart failure, heart failure, liver cirrhosis

Health condition

hyponatriemie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aquaporins, Sodium transporters, Urinary exosomes

Outcome measures

Primary outcome

Expression profiles of water and sodium transporters in urinary exosomes.

Secondary outcome

Not applicable.

Study description

Background summary

Since 1995 it has been known that renal transporters are excreted into the urine (Kanno et al, N Engl J Med 1995). However, only in 2004 it has become clear how these transporters are excreted into the urine (Pisitkun et al, Proc Natl Acad Sci USA 2004). The renal transporters are present in so-called urinary exosomes.

Study objective

To investigate whether the expression of renal water and sodium transporters in urinary exosomes is different in compensated versus decompensated liver and heart disease.

Study design

Patients will be recruited from the outpatient clinics and the clinics of cardiology and hepatology. Compensated and decompensated disease will be defined on the basis of the serum sodium level (cut-off 130 mmol/l). Healthy volunteers will be recruited through untargeted advertisement. Blood and urine

will be collected via standardized procedures. Subsequently, urinary exosomes will be isolated and the expression of water and sodium transporters will be analyzed through immunoblotting.

Study burden and risks

Phlebotomy, burden: mild, risks: hematoma, vasovagal syncope.
Collection of urine, burden: minor, risks: none.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients with heart or liver disease whose disease is not associated with renal disease and

who are not taking medication that can cause kidney damage. Healthy volunteers without heart or liver disease, who are not taking medication.

Exclusion criteria

Patients with heart or liver disease whose disease is associated with renal disease or who are taking medication that can cause kidney damage. Healthy volunteers who are taking medication.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	25-02-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL26739.078.09