# 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 reviewApproved WMOStatusRecruitingHealth condition typeOther 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:** Aguaporins, 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

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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**

## **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040 3000 CA Rotterdam

NL

#### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040 3000 CA Rotterdam NL

# **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

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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