ELISA to measure urinary exosomal content: proof of principle study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43613

Source
ToetsingOnline

Brief title
Measuring protein content of urine vesicles

Condition

- Other condition

Synonym
N.A.

Health condition

Fysiologische studie - testen van methodiek

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: ELISA, Exosomes, Urine

Outcome measures

Primary outcome

The primary outcome will be a change in urine osmolality after fasting and

water loading.

Secondary outcome

Change of urine exosomal aquaporin-2 and NCC between fasting and after water

loading. Furthermore the number of excreted exosomes.

Study description

Background summary

Urinary exosomes are small vesicles secreted by all epithelial cells lining the nephron. Their protein content reflects the state of the cells they originate from, allowing their measurement as a non-invasive biomarker for kidney physiology and pathology. Current methods to measure exosomal content relies on ultracentrifugation, which is a time-consuming method requiring large volumes of urine. A better approach would be the use of an enzyme linked immunosorbent assay (ELISA) to measure exosomal content.

Study objective

This proof of principle study is designed to study the excretion of two well-studied transporters, Aquaporin-2 (AQP-2) and the sodium chloride cotransporter (NCC), in urinary exosomes. Both are sensitive to water homeostasis, so that during water deprivation or water loading they are increased or decreased, respectively. Our goal is to measure AQP-2 and NCC in healthy volunteers after fasting and waterloading. We would like to see if these changes are detected using our ELISA. Furthermore (in the amendment), we

would like to determine usability of the technique as normalization method by counting exosomes using a newly available method.

Study design

Volunteers will be asked to fast for 14 hours and subsequently drink water (20 mL/kg in 30 minutes). Urine will be collected at 2 time points during fasting (10h and 12h) and 3 time points after water loading (1h, 2h and 4h).

Intervention

14 hour fasting and water loading (20 mL/kg body weight in 30 minutes)

Study burden and risks

An overnight water deprivation test will be performed, which may be inconvenient for the patient. The risk of fasting includes dehydration and related symptoms, such as excessive thirst, change in mental state and decrease of blood pressure. However, the risk of dehydration after 14 hour fasting is negligible. The risks for consuming a water load include electrolyte imbalances, such as a hyponatremia. In healthy subjects, that are subjected to 20mL/kg body weight, this risk is negligible.
There are no direct benefits associated with participation for the individual participant.

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

Have the capacity to understand and willingness to sign an informed consent form.
Aged 18-30 years

Exclusion criteria

- Use of medication
- History of diabetes insipidus, diabetes mellitus, adrenal deficiency, thyroid disease or chronic kidney disease
- Alcohol abuse
- Urinary tract infection or menstruation at the time of inclusion
- Pregnancy or breast feeding

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2015

Enrollment:	4
Type:	Anticipated

Ethics review

Approved WMO Date:	02-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-01-2017
Application type:	Amendment
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	NL52107.078.15