Pathophysiological mechanisms of impaired urinary concentrating ability in hypothyroidism.

Published: 24-04-2014
Last updated: 20-04-2024

To study the extent of impaired urinary concentrating ability in hypothyroidism as well as the pathophysiological mechanisms involved before and after adequate treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON40625

Source
ToetsingOnline

Brief title
urinary concentrating ability in different thyroid states.

Condition

- Thyroid gland disorders
- Renal disorders (excl nephropathies)

Synonym
hypothyroidism, urinary concentrating ability

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: differentiated thyroid cancer, hypothyroidism, pathophysiology, urinary concentrating ability

Outcome measures

Primary outcome

The primary outcome will be a significant difference in maximal urine

osmolality after water deprivation in euthyroid and hypothyroid state.

Secondary outcome

The secondary outcome is a difference in heart rate, urinary water and salt

transporter excretion in urinary microvesicles (both protein and RNA abundance)

and vasopressin/ copeptin levels after water deprivation.

Study description

Background summary

Hypothyroidism is associated with impaired urinary concentrating ability. The effect of treatment as well as the mechanism involved have not been adequately studied in humans.

Study objective

To study the extent of impaired urinary concentrating ability in hypothyroidism as well as the pathophysiological mechanisms involved before and after adequate treatment.

Study design

Single centre intervention study. During regular clinical follow-up, patients with differentiated thyroid cancer are subject to severe hypothyroidism before I-131 therapy, whereas they have relatively normal thyroid hormone levels before thyroidectomy and after I-131 therapy when receiving thyroid hormone substitution therapy with levothyroxine. Therefore, these patients provide an excellent model to study the consequences of variations in thyroid state. During two regular clinical visits, patients will undergo a water deprivation

test as well as blood and urine analysis.

Intervention

14 hour fasting.

Study burden and risks

Serum will be obtained by collecting two additional tubes of blood when blood is drawn as part of the regular clinical follow-up. Also, one spot urine sample will be collected.
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.
There are no direct benefits associated with participation for the individual patients.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patient with differentiated thyroid carcinoma
Have the capacity to understand and willingness to sign an informed consent form.
Aged 18-65 years
Estimated kidney function, eGFR >60 mL/min per 1.73 m2

Exclusion criteria

Alcohol abuse
Other malignancy
Clinically relevant active systemic disease (such as autoimmune or infectious diseases)
Pregnancy
Use of drugs interfering with thyroid hormone metabolism (e.g. antiepileptic drugs, amiodarone, and lithium) or influencing renal concentration capacity (i.e. diuretics)
Other primary thyroid disease
History of diabetes insipidus, diabetes mellitus, adrenal deficiency, chronic kidney disease
Urinary tract infection or menstruation at the time of inclusion

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2014

Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2014
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	NL48144.078.14