Copeptin as a possible predictor of developing diabetes insipidus following transsphenoidal pituitary surgery

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON41983

Source
ToetsingOnline

Brief title
Copeptin and diabetes insipidus

Condition

- Hypothalamus and pituitary gland disorders

Synonym
ADH deficiency/or resistance

Research involving
Human

Sponsors and support

Primary sponsor: Inwendige Geneeskunde/Endocrinologie
Source(s) of monetary or material Support: Ministerie van OC&W,Thermofisher

Intervention

Keyword: ADH, biomarker, copeptin, diabetes insipidus

Outcome measures

Primary outcome

The difference in copeptin levels between patients who develop DI and those who do not at several timepoints following surgery.

We will also determine a cut-off level of copeptin which can be used to predict development of DI post surgery.

Secondary outcome

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Study description

Background summary

Approximately 20-30% of patients develop central diabetes insipidus (DI) following transsphenoidal surgery. DI can lead to severe morbidity and prolong inpatient treatment. Early diagnosis of DI is thus important. Diagnosis of DI nowadays depends on monitoring urine production and measurement of plasma sodium and osmolality, which is labour-intensive.
Copeptin (CT-proADH) is a stable precursor of ADH and has been suggested as a biomarker of development of DI. We hypothesize that patients who develop DI following transsphenoidal surgery have reduced copeptin levels compared to patients who do not develop DI.

Study objective

We aim to investigate whether copeptin can be used as an early postoperative marker for development of DI. We will measure copeptin levels in patients just prior to and following transsphenoidal surgery to be able to investigate whether copeptin levels are indeed reduced in patients who develop DI. Besides we will determine a cut-off value of copeptin for identification of DI patients (with reduced copeptin secretion) post surgery.

Study design

Observational study, multicentre approach

Study burden and risks

This study involves 12x blood sampling (venepuncture, 12x4 ml), during scheduled inpatient treatment and once during scheduled outpatient control, 3 weeks following surgery. Eight of 12 blood samplings will be performed during regular blood sampling (thus require no additional venepuncture). There will be no additional site visits, physical examinations or other tests. Participation in this study will not influence regular treatment and no risks will be expected from additional blood sampling.

Contacts

Public
Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

-adult patiënts scheduled for endoscopic transnasal pituitary surgery

Exclusion criteria

- patients <18 y old
- wilsonbekwamen
- patients with pre-existent diabetes insipidus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL50722.018.14