Quantitative and qualitative analysis of cortisol and adrenocorticotrophic hormone (ACTH) secretion in patients with subclinical Cushing syndrome (SCS) and bilaterally enlarged adrenal glands

Published: 07-09-2007
Last updated: 08-05-2024

To investigate cortisol and ACTH rhythm (frequency, amplitude and regularity of cortisol and ACTH secretory pulses) in patients with SCS and bilateral adrenal involvement.

Ethical review	Approved WMO
Status	Pending
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON31116

Source
ToetsingOnline

Brief title
Cortisol and ACTH secretion in SCS

Condition

- Adrenal gland disorders

Synonym
Subclinical Cushing Syndrome, Subclinical Hypercortisolism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ACTH, Cortisol, Rhythm, Subclinical Cushing syndrome

Outcome measures

Primary outcome

Cortisol and ACTH rhythm expressed as frequency/amplitude and regularity of cortisol and ACTH secretory pulses.

Secondary outcome

Comparance of cortisol and ACTH rhythm expressed as frequency/amplitude and regularity of cortisol and ACTH secretory pulses of patients with subclinical cushing syndrome to patients with full-blown Cushing syndrome and healthy controls, previously investigated by means of 10 minute sampling in the LUMC in Leiden.

Study description

Background summary

Patients with subclinical Cushing syndrome (SCS) have autonomous, possibly increased cortisol secretion without the evident clinical features of Cushing syndrome.
Despite the lack of the typical Cushing fenotype, long term morbidity has been reported in SCS patients, related to disturbed cortisol secretion.
Therefore, it is important to know to what extent cortisol and ACTH secretion are disturbed, and whether therapeutic intervention is necessary. Especially in patients with SCS and bilateral adrenal pathology this information is important because both therapeutic options have major impact (surgery: bilateral adrenalectomy will result in Addison (hypocortisolism), medically: ketoconazol produces frequent and potential side effects).

In patients with Cushing syndrome (both the pituitary-dependent and the adrenal-depent type) both the rhythm as well as the regularity of cortisol and ACTH secretion, as determined by obtaining a 24-hour profile, is disturbed.
In patients with SCS such a 24-hour profile of cortisol and ACTH secretion has never been performed.
The results will give more insight in the (disturbance of) cortisol and ACTH profile of SCS patients. This will help to make a decision with regard to the necessity of therapeutic intervention.

Study objective

To investigate cortisol and ACTH rhythm (frequency, amplitude and regularity of cortisol and ACTH secretory pulses) in patients with SCS and bilateral adrenal involvement.

Study design

Blood sampling every 10 minutes for 24 hours and determination of cortisol and ACTH in patients with SCS with bilateral adrenal involvement and compare these to previously investigated controls and patients (with pituitary-dependent and adrenal-dependent forms of Cushing disease).

Study burden and risks

The burden for participating patients is a venapuncture to determine Hemoglobin, and if Hemoglobin is normal, a 36 hours hospital stay, with insertion of an indwelling iv cannula once, and withdrawal of blood from the cannula every 10 minutes. In total an amount of 360 ml blood will be withdrawn, this is less than the amount of blood withdrawn from blood donors (500 ml in 15 minutes). There is no risk for the patients participating.

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

Patients known at the outpatient clinic of Endocrine Diseases in the UMCN St. Radboud, with subclinical Cushing syndrome with bilateral adrenal pathology

Exclusion criteria

Patients with SCS in whom adrenalectomy has been done, and patients with SCS and unilateral adrenal involvement and patients with SCS due to pituitary pathology

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL17355.091.07