Recovery of hypothalamic-pituitary-adrenal axis during glucocorticoid tapering in ANCA- associated vasculitis, a pilot study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29371

Source
Nationaal Trial Register

Brief title
CURVE

Health condition

Glucocorticoid tapering
ANCA associated vasculitis
hypothalamic-pituitary-adrenal axis

Glucocorticoid afbouwschema
Hypothalamus-hypofyse-bijnier as

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

The main study endpoint is change in peak cortisol levels at acrophase during a glucocorticoid tapering regime

Secondary outcome

Secondary endpoints include the effect on cortisol ratios or indices of cortisol production, which might prove to be helpful
in assessing adrenal function or might be suggestive for impaired recovery or adrenal insufficiency. Furthermore, the
effect of the tapering regime on melatonin rhythm, cytokine profile, complaints compatible with secondary glucocorticoidinduced
adrenal insufficiency, quality of life, fatigue and sleep quality.

Study description

Background summary

Glucocorticoids are extensively used for a wide-variety of diseases. In many diseases, amongst others rheumatic
diseases, high-dose glucocorticoids are administered to control disease activity. These supra-physiological glucocorticoid
doses suppress the endogenous cortisol production and disrupt the circadian rhythm of the hypothalamic-pituitary-adrenal
(HPA) axis. In order to prevent relapses and to give the adrenal glands time to recover the endogenous cortisol
production, tapering regimes are used for glucocorticoid withdrawal. However, no longitudinal studies have investigated
the effect of a tapering regime on the recovery of the circadian rhythm of the HPA axis and the relation with complaints
possibly compatible with secondary adrenal insufficiency.
The primary aim of this study is to investigate the recovery of the circadian rhythm of the hypothalamic-pituitary-adrenal
axis during a glucocorticoid tapering regime. Secondary objectives include the effect of a tapering regime on melatonin
rhythm, cytokine profile, complaints compatible with secondary glucocorticoid-induced adrenal insufficiency and quality of
life, fatigue and sleep quality

Study objective

Recovery of the HPA axis shows interindividual differences. Recovery can be monitored using saliva sampling and monitoring could prevent complaints during tapering of glucocorticoids.

Study design

The 24-hour sampling will take place at prednisolone dosages of 10 mg (T1 =2 weeks), 7,5 mg (T2= 2 weeks), 5 mg (T3= 6 weeks), 2,5 mg (T4= 8 weeks)
and 4 weeks (T5= 12 weeks) and 3 months after stop of the glucocorticoids (T6= 20 weeks)

Intervention

No intervention is planned. Participants will sample saliva during a standard glucocorticoid tapering regime.

Contacts

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Eligibility criteria

Inclusion criteria

Patient with newly diagnosed granulomatosis with polyangiitis or microscopic polyangiitis who received standard glucocorticoid induction protocol

Patients with a relapse of granulomatosis with polyangiitis or microscopic polyangiitis who received standard glucocorticoid induction protocol
Provide written informed consent

Exclusion criteria

Age < 18 years
Use of > 7,5 mg of glucocorticoids for more than 4 consecutive weeks within 6 months prior to diagnosis of disease or disease relapse.
Premenopausal women (because of effects of estrogens on cortisol binding globulin and because of differences in HPA axis functioning in the luteal or follicular phase)
Postmenopausal women using oral contraceptives or estrogen replacement therapy (since estrogens increase the hepatic production of cortisol binding globulin)
A history of endogenous hypocortisolism or hypercortisolism prior to this study
Work in shifts or have a documented severely disturbed sleep pattern
Not able to perform saliva sampling
Patients who have a significant other medical condition (e.g. hepatic, respiratory, cardiovascular or gastrointestinal) which, in the opinion of the investigator, may interfere with the interpretation of results or efficacy evaluations
Traveled through time zones with more than two hours time difference within the last month prior to this study
Use of exogenous melatonin within the last 6 months prior to this study
Subject with a documented depression
Subjects who are in a stressful situation (for example, death of a relative), which in the opinion of the investigator, may interfere with the interpretation of results or efficacy evaluations

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015

Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion
Date: 08-02-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40671
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4850
NTR-old	NTR4966
CCMO	NL49307.042.14
OMON	NL-OMON40671

Study results