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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29371

Bron
Nationaal Trial Register

Verkorte titel
CURVE

Aandoening

Glucocorticoid tapering
ANCA associated vasculitis
hypothalamic-pituitary-adrenal axis

Glucocorticoid afbouwschema
Hypothalamus-hypofyse-bijnier as

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2015

Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-02-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40671
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten