Inhalation or nasal corticosteroids and prevalence of hypothalamic-pituitary-adrenal axis suppression in HIV-infected patients

Published: 10-03-2015
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Primary objective:a. How often do inhalation or nasal corticosteroids lead to suppression of the HPA- axis in HIV-treated patients? Secondary objectives:b. Are other variables associated with the HPA-axis suppression? c. Are cortisol measurements in...

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

Summary

ID

NL-OMON42012

Source
ToetsingOnline

Brief title
incorporate

Condition

- Adrenal gland disorders

Synonym
adrenal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W,AIDS fonds en Radboud UMC afdelingen Apotheek en Toxicologie-farmacologie

Intervention

Keyword: adverse effect, corticosteroid, hypothalamic-pituitary-adrenal axis suppression

Outcome measures

Primary outcome

Proportions of persons with a low morning plasma cortisol or low cortisol after

an ACTH stimulation test.

Secondary outcome

b. Proportions of persons with a low morning plasma cortisol or low cortisol

after an ACTH stimulation test, stratified e.g. by kind of inhalation

corticosteroid, dosage of local corticosteroid and use/no use of CYp3A4

inhibitor.

c. Correlation between cortisol in plasma and hair cortisol.

Study description

Background summary

Case reports describe suppression of the hypothalamic-pituitary-adrenal (HPA) axis caused by local corticosteroids, most often with inhalation corticosteroids. The exact prevalence is not known. Early recognition is important, because suppression of the HPA-axis can lead to significant morbidity and mortality. Suppression of the HPA axis might occur more often when a CYP3A4 inhibitor, e.g. ritonavir, is used next to the local corticosteroid, a combination often used by HIV-patients. Cortisol can be determined in hair. This non-invasive analysis could help in diagnosis of suppressed HPA-axis.

Study objective

Primary objective:

a. How often do inhalation or nasal corticosteroids lead to suppression of the HPA- axis in HIV-treated patients?
Secondary objectives:
b. Are other variables associated with the HPA-axis suppression?
c. Are cortisol measurements in hair as reliable as serum cortisol or an ACTH stimulation test to diagnose suppression of the HPA axis?

Study design

cross-sectional explorative study

Intervention

an ACTH stimulation test, cortisol measurements in blood and hair.

Study burden and risks

Each person will be screened with a history and a short physical examination. A venous cannula will be inserted for obtaining blood for the plasma cortisol and for the ACTH stimulation test. An ACTH stimulation test has no major complications. A piece of hair is cut for cortisol hair analysis. The risks and burden are minimal, while the future benefits could be great since suppression of the endogenous HPA- axis can be associated with morbidities like hypertension or osteoporosis and can even lead to an adrenal crisis when the local corticosteroid is stopped.

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

- Receive a treatment for HIV-infection
- > 18 years old
- Current usage of inhalation or nasal corticosteroids
- Willing to give informed consent

Exclusion criteria

- Known adrenal insufficiency
- Concurrent use of topical corticosteroids, usage of oral corticosteroids in the last three months. Intramuscular or intra-articular corticosteroid injections in the last year.
- Contra-indications for tetracosactide: allergy for tetracosactide, Cushings*s syndrome, refractory heart failure, peptic ulcer, acute psychosis, adrenogenital syndrome
- Pregnant female or breast-feeding female.
- Use of oral contraceptives, since these can heighten the cortisol-binding globulin

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2016
Application type:	Amendment
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	NL51711.091.14