The influence of oral contraception on the 1 mg overnight dexamethasone suppression test

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1. Examen if the outcome of the 1 mg Overnight Dexamethasone suppression test is influenced by the use of oral contraception.2. Examen how many weeks after ceasing the use of orale contraception the 1 mg Overnight Dexamethason suppression test is...

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

Summary

ID

NL-OMON36254

Source
ToetsingOnline

Brief title
OAC-DEX

Condition

- Adrenal gland disorders

Synonym
Cushing's syndrome, hypercorticism

Research involving
Human

Sponsors and support

Primary sponsor: Slingeland Ziekenhuis
Source(s) of monetary or material Support: onderzoeksfonds maatschap Interne geneeskunde

Intervention

Keyword: 1 mg overnight, contraception, Cushing's syndrome, dexamethasone suppression test

Outcome measures

Primary outcome

Serum cortisol after the 1 mg overnight dexamethasone suppression test during

use of OAC and after one and six weeks of ceasing of contraception.

Urinary and salivary cortisol during use of OAC and after one and six weeks of

ceasing of contraception.

Secondary outcome

If necessary: CBG, ACTH, free cortisol, FSH, LH

Study description

Background summary

The use of oral contraceptives possibly influences the outcome of the 1 mg Overnight Dexamethasone suppression test.
The 1 mg Overnight Dexamethasone suppression test is a frequently used diagnostic test to exclude hypercortisolism. 1mg dexamethason is given at 23:00 and the serum cortisol is measured the morning after at 08:00h. Oral contraception increases protein boudning of cortisol, as a result a falsely elevated serum cortisol may be measured. Oral contraception are used frequently. As a result of this, the interpretation of the 1 mg Overnight Dexamethasone suppression test isoften hindered in clinical practice. The literature is unambiguous about the inter pretation of the 1 mg Overnight Dexamethasone suppression test when oral contraception is used. Advised is to withdraw oral contraception before doing the 1 mg Overnight Dexamethasone suppression test. There is no consensus about the duration of withdrawing of oral contraception.
This study aims to determine if there is a differende in the serum cortisol with and without use of oral contraception and if so, how long the use of oral contraception should be withdrawn to exclude this influence

Study objective

1. Examen if the outcome of the 1 mg Overnight Dexamethasone suppression test is influenced by the use of oral contraception.
2. Examen how many weeks after ceasing the use of orale contraception the 1 mg Overnight Dexamethason suppression test is normalized.
3. Examen if urinary and salivary cortisol are good alternatives for the screening on hypercorticism during use of contraception.

Study design

Intervention study: cross over trial

Intervention

Performing the 1 mg Overnight Dexamethasone suppression test at the end of the third week of oral contraception. Afterwards the use of oral contraception is ceased and is the 1 mg Overnight Dexamethason suppression test repeated at the end of successively the first, and sixth week after ceasing oral contraceptive. Also, urinary and salivary cortisol are collected three times for measurement of cortisol

Study burden and risks

- Ceasing orale contrapceptives, consequently if no use of other contraceptives: risk of pregnancy
- Risk of the 1 mg Overnight Dexamethasone suppression test. When 1 mg Dexamethasone is taken once there are no adverse reactions expected
- 3x venepuncture and once urinary pregnancy test
- 4 visits to the hospital

Contacts

Public
Slingeland Ziekenhuis

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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

use of oral contraception

Exclusion criteria

Cushing's syndrome, psychiatric diseases, alcohol use of more than 7 units/week, pregnancy, steroid medication

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):	15-11-2011
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	04-04-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-07-2012
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	NL31515.091.11