The effect of discontinuing estrogen containing oral contraceptives on corticosteroid-binding globulin and total cortisol concentrations

Published: 11-12-2024
Last updated: 18-01-2025

In this study we look at how long it takes for the levels of certain hormones and hormone-binding proteins to normalizediscontinuation of COC use, in particular corticosteroid-binding globulin.

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

Summary

ID

NL-OMON57226

Source
ToetsingOnline

Brief title
CBG normalization after cessation of COC's.

Condition

- Adrenal gland disorders

Synonym
Syndromes/disease with high or low serum cortisol levels

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: reserves van de afdeling

Intervention

Keyword: CBG, combined oral contraceptives, normalization

Outcome measures

Primary outcome

CBG en total cortisol concentrations

Secondary outcome

Secundary: VDBP -vitamin D; TBG - T4, T3; SHBG - testosterone; IGFBP3- IGF1.

Tertiairy: albumin, prolactin, fT3, fT4, TSH, estradiol, progesterone, LH, FSH.

HCG at first blood sampling

Study description

Background summary

Due to the increase in corticosteroid-binding globulin (CBG) and therefore total cortisol when using oral estrogens,
oral estrogen-containing contraceptives (COC's) are discontinued during endocrine function tests that measure total cortisol. It's unclear
how long after discontinuation of oral estrogens CBG and total cortisol concentrations normalize.

Study objective

In this study we look at how long it takes for the levels of certain hormones and hormone-binding proteins to normalize
discontinuation of COC use, in particular corticosteroid-binding globulin.

Study design

Weekly blood samples in the morning for a total of eight weeks: 2 weeks while taking the contraceptive pill and 6 weeks after discontinuation of the contraceptive pill. Additionally, participants will be asked about relevant history / medication use and height and weight will be measured.

Study burden and risks

Burden consists mainly in the form of 8 visits to the Amsterdam UMC, AMC location, with 8 additional venipunctures. Venipunctures have very minor risks other than hematomas and discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

=/> 18 years old, female, stopping combined oral contraceptive use for at least 6 weeks

Exclusion criteria

Switching to other hormonal contraceptives after taking COC's; contra-indications to quit COCs; biological factors that affect CBG concentrations (severe kidney/liver disease, active malignancy, hyperthyroidism); use of insulin, systemic glucocorticoids, mitotane, SERMs. If patient gets pregnant during study period: exclusions of measurements after pregnancy.

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):	01-12-2024
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	11-12-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL87932.018.24