The thrombogenicity of the dienogest/estradiol valerate-containing oral contraceptive (Qlaira®)

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To measure APC resistance and SHBG levels as indicators of the risk of venous thrombosis during use of the new developed combined oral contraceptive containing dienogest/estradiolvalerate (Qlaira®) compared with a combined oral contraceptive...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON35104

Source
ToetsingOnline

Brief title
Thrombogenicity of Qlaira®

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
blood clot, Venous thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: "eigen potje" van een van de hoofdonderzoekers

Intervention

Keyword: APC-resistance, Dienogest/estradiol valerate, Oral contraceptive, SHBG, Thrombogenicity

Outcome measures

Primary outcome

Thrombin generation based-APC-resistance and SHBG.

Secondary outcome

Factor V Leiden and prothrombin mutation.

Study description

Background summary

During use of the combined oral contraceptive, there is a 3-6 times increased risk of venous thrombosis. The dose of estrogen and the type of progestagen are influencing this risk. The increased risk of venous thrombosis during use of a combined oral contraceptive can be (partly) biologically explained by a by the pill induced increased resistance of Activated Protein C (APC). An increased resistance for the anticoagulant action of APC is a risk factor of venous thrombosis.
In the past, research showed that combined oral contraceptives with a higher risk of venous thrombosis induce a higher APC-resistance than low-risk combined oral contraceptives.
Sex Hormone Binding Globuline (SHBG) is a transport protein which transports estrogen and testosterone, and has a higher concentration in blood during use of combined oral contraceptives. In various investigations, SHBG showed to be a marker for the risk of venous thrombosis during use of combined oral contraceptives as well.
The risk of venous thrombosis during use of the recently developed combined oral contraceptive with dienogest/estradiolvalerate (Qlaira®) is not investigated yet.

Study objective

To measure APC resistance and SHBG levels as indicators of the risk of venous thrombosis during use of the new developed combined oral contraceptive containing dienogest/estradiolvalerate (Qlaira®) compared with a combined oral

contraceptive containing levonorgestrel/ethinylestradiol (Microgynon-30®).

Study design

80 healthy, voluntarily, female persons will be randomized in two groups. The study is not blinded. The first group will use dienogest/estradiolvalerate (Qlaira®) and the second group will use levonorgestrel/ethinylestradiol (Microgynon-30®) as combined oral contraceptive. The contraceptives will be provided by the investigators.
Before the subjects start to use the contraceptives, they have to fill in a survey, and a blood sample will be taken. The contraceptives will be used for three months. In the third month, four blood samples will be taken at day 2, 7, 24 and 26 of the cycle. This is one blood sample per phase of the fourphase oral contraceptive dienogest/estradiolvalerate (Qlaira®). We*ll also take blood samples of the users of levonorgestrel/ethinylestradiol (Microgynon-30®) at the same days, as comparison.
At the last appointment, the subjects have to fill in a survey again. After these three months, the investigation ends for the subjects.
We*ll measure all the determinants in the blood samples.

Intervention

ienogest/estradiolvalerate-containing combined oral contraceptive or a levonorgestrel/ethinylestradiol-containing combined oral contraceptive

Study burden and risks

The subjects have to visit the Leiden University Medical Centre (LUMC) five times for the take of blood samples. Two times during these visits, they also have to fill in a survey. The total time in the LUMC is maximal 60 minutes. Taking blood is minimal invasive and doesn't have a lot of risks. There could be a complication, like a hematoma or pain at the prick spot, but these complications are temporary and don't give any healthrisks. Another risk are the known side-effects of oral contraceptives as described by the WHO and Dutch Society of Gynaecologists.

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

Women, age 18-35 years, the wish to use dienogest/estradiol valerate or levonorgestrel/ethinylestradiol as oral contraceptive.

Exclusion criteria

People who are legally incapable, contra-indications for the use of oral contraceptives as described by the WHO and Dutch Society of Gynaecologists, pregnancy during or in the three months before the trial, use of medication which can influence coagulation, chronic/acute illness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2010
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Microgynon 30
Generic name:	levonorgestrel/ethinylestradiol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Qlaira
Generic name:	dienogest/estradiol valerate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	24-02-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-04-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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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
EudraCT	EUCTR2010-018590-38-NL
CCMO	NL31451.058.10