The risk of venous thrombosis during use of Qlaira (R).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21448

Source
NTR

Health condition

Veneuze trombose, venous thrombosis.
Anticonceptie, contraception

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

Sex-Hormone Binding Globulin (SHBG) and Activated Protein C-resistance (APC-resistance).

Secondary outcome

N/A

Study description

Background summary

To determine the risk of venous thrombosis during use of the dienogest/estradiolvalerate oral contraceptive (Qlaira), APC-resistance and SHBG (as surrogate markers for venous thrombosis) will be measured at baseline and after three months of use of the oral contraceptive. We will compare dienogest/estradiolvalerate with levonorgestrel/ethinylestradiol (Microgynon-30).
80 healthy, competent, 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®) during three months. 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. After these three months, the investigation ends for the subjects. We'll measure APC-resistance and SHBG in the blood samples in one run, after completion of the blood collection.

Study objective

The dienogest/estradiolvalerate containing oral contraceptive is more thrombogenic than the levonorgestrel/ethinylestradiol containing oral contraceptive (microgynon-30).

Study design

1. Baseline;

2. 4x in the third cycle on day 2, 7, 24, 26 of the pill-cycle.

Intervention

Use of Qlaira or Microgynon-30 during 3 cycles.

Contacts

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Eligibility criteria

Inclusion criteria

Competent women, 18-35 years with the wish to use an oral contraceptive (Qlaira or Microgynon-30).

Exclusion criteria

1. People who are legally incapable;

2. Contra-indications for the use of oral contraceptives as described by the WHO and Dutch Society of Gynaecologists;

3. Pregnancy in the three months before the trial;

4. Use of medication which can influence coagulation;

5. Chronic/acute illness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-05-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion Date:	10-05-2010
Application type:	First submission

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
NTR-new	NL2228
NTR-old	NTR2354
Other	CME LUMC : P10.041
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results