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

Public

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Scientific

Postbus 9600

M. Raps

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 wordt niet meer aangevraagd.

Study results