A prospective, randomized, double-blind parallel-arm, placebo-controlled study to assess the effects on ovarian activity of a combined oral contraceptive pill when preceded by the intake of ellaOne® (ulipristal acetate 30 mg) or placebo.

Published: 01-02-2012
Last updated: 26-04-2024

Primary objective:To compare the effects of quick starting a combined oral contraceptive on follicular growth and hormonal parameters after ellaOne® or placebo intake.Secondary objective:To compare the effects of quick starting a combined oral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37370

Source
ToetsingOnline

Brief title
Quickstart combined OAC after emergency contraception

Condition

- Other condition

Synonym
contraception, fertility control

Health condition

contraception

Research involving
Human

Sponsors and support

Primary sponsor: HRA Pharma
Source(s) of monetary or material Support: industry

Intervention

Keyword: emergency contraception, oral contraception, ovarian activity, placebo controlled

Outcome measures

Primary outcome

- transvaginal ultrasound results, i.e. the mean diameter iin two axes of the

largest follicle in each ovary and anteroposterior endometrial thickness

- progesterone levels in serum

- estradiol levels in serum

Secondary outcome

- vaginal bleeding pattern

- adverse events

Study description

Background summary

In a Cochrane review women who had further episodes of intercourse in the same cycle as emergency contraception (EC) use had a two- to three-fold higher risk of pregnancy (Cheng, 2008). This raises the importance of initiating a regular contraception immediately after EC is used -a practice known as *Quick start*. Since ulipristal acetate (UPA) is a progesterone receptor modulator, there is concern that quick starting after UPA could alter the effectiveness of hormonal contraception and vice versa.

The Clinical Effectiveness of the Faculty of Sexual and Reproductive Healthcare (FSRH) advises 14 days of additional barrier methods if women are quick starting the combined oral contraceptive pill (COCP) after using ellaOne® (FSRH 2010). The FSRH also advises that for women who start routine use of the COCP at any time in cycle other than within the first five days (and who have not taken UPA), 7 days of COCP are required before it can be relied on for contraception (FSRH 2010).

Further research is needed on the effects of quick starting hormonal contraception after the intake of UPA, so women can be advised regarding the use of additional non-hormonal contraception.

Currently no interaction data are available about use of ellaOne® with regular hormonal contraceptives. Because UPA binds the progesterone receptor with high affinity, it may interfere with the action of progestogen-containing medicinal products, such as combined hormonal contraceptives. The half-life of UPA is 32.4 hours, and most of the drug is eliminated by 1 week and the interaction with hormonal contraception is likely to be clinically insignificant by this time. Starting contraception immediately after EC, rather than waiting for the next menses, should reduce a woman*s risk of pregnancy.

Study objective

Primary objective:
To compare the effects of quick starting a combined oral contraceptive on follicular growth and hormonal parameters after ellaOne® or placebo intake.

Secondary objective:
To compare the effects of quick starting a combined oral contraceptive on menstrual bleeding patterns and tolerability after ellaOne® or placebo intake.

Study design

The study is a multi-center, double-blind, randomized, placebo-controlled trial in healthy female volunteers.

Intervention

Participants will receive either ellaOne® or placebo during a spontaneous cycle, once the dominant follicle is lager than 13 mm. The combined oral contraceptive will be started the day after and taken once daily for 21 days.

Study burden and risks

At screening: physical and gynaecological examination including transvaginal ultrasonography (TVUS).

During treatment: at most of the visits TVUS and venapunction.
Daily diary recording
Urine sampling at home (16 times).
The use of additional non-hormonal contraception.

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

- healthy women
- age 18-35 years
- not at risk for pregnancy

Exclusion criteria

- contraindication for use of combined oral contraceptives (e.g. history of venous or arterial thromboembolic disease
- clinically relevant findings (physical and gynecological examination, blood pressure)
- irregular mentrual cycle
- intake of medication thought to interact with ellaOne or combined oral contraceptives

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2012
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ellaOne
Generic name:	ulipristal acetate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Microgynon 30
Generic name:	ethinylestradiol/levonorgestrel

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-02-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-02-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2011-005573-23-NL
CCMO	NL39222.056.12