Multicenter, open-label, randomized study to evaluate inhibition of ovulation during treatment with three transdermal patch formulations containing 0.55 mg ethinylestradiol (EE) and 2.10 mg gestodene (GSD) or 0.35 mg EE and 0.67 mg GSD or 0.275 mg EE and 1.05 mg GSD in healthy young female volunteers over a period of 3 treatment cycles

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Objective of this study is the evaluation of contraceptive patches with EE and GSD. The inhibition of ovulation of three different patch formulations will be evaluated. Secondary objectives are the course of gonadotropins, estradiol and progesterone...

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

Summary

ID

NL-OMON34076

Source
ToetsingOnline

Brief title
Pharmacodynamic and -kinetic study of 3 transdermal EE and GSD formulations

Condition

- Other condition

Synonym
contraception, Fertility control

Health condition

contraception

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ethinylestradiol, gestodene, ovulation inhibition, patch

Outcome measures

Primary outcome

The proportion of subjects with ovulation in at least one of the treatment

cycles 2 and 3.

Secondary outcome

* course of FSH, LH, estradiol and progesterone levels

* follicle size

* pharmacokinetics of EE, GSD and SHBG in treatment cycle 2 and 3

Study description

Background summary

Transdermal drug application systems for hormones have been successfully used

in treatment of peri- and postmenopausal complaints for several years. The hormones used can be applied to achieve contraception, but until now there is only 1 patch available on the market. Because a patch has to be replaced only once a week, compliance is improved compared to oral contraceptives. Furthermore, the contraceptive efficacy is not reduced during vomiting and diarrhoea. Blood levels of the applied hormones are more constant and show less intra-individual variation than during use of an oral contraceptive.
In the present study, ovulation inhibition will be investigated following application of three contraceptive patches with different contents of the hormones ethinyl estradiol (EE) and gestodene (GSD).

Study objective

Objective of this study is the evaluation of contraceptive patches with EE and GSD. The inhibition of ovulation of three different patch formulations will be evaluated. Secondary objectives are the course of gonadotropins, estradiol and progesterone levels as well as pharmacokinetic parameters.

Study design

A 3-arm design, open-label, randomized. 1 pre-treatment cycle, 3 treatment cycles, 1 follow-up cycle. There will be stratification in 2 BMI groups (1 group with BMI between 18 and 30 kg/m2 and 1 group with BMI higher than 30 kg/m2).

Intervention

3 cycles use of patches in 3 different dosage groups. 21 days per treatment cycle, i. e. 3x7 days patch wearing followed by a patch free interval of 7 days.

Study burden and risks

At screening: physical exam, gynecological exam including vaginal ultrasound, cervical smear and venous puncture.

During treatment periods, there is a venous puncture and a vaginal ultrasound in most visits.

Attachment and removal of patch will be checked.

Daily diary recording.

Use of additional non-hormonal contraception.

The risks of the study medication are similar to those of an oral

contraceptive.

Contacts

Public
Bayer

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DE
Scientific
Bayer

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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 female volunteers
age 18 - 35 years (smoker not older than 30 years, inclusive)
ovulatory pre-treatment cycle

Exclusion criteria

- Contraindications for use of combined (estrogen/gestodene) contraceptive (e.g. history of

venous or arterial thromboembolic disease)
- Regular intake of medication other than Oral Contraception
- Clinically relevant findings (blood pressure, physical and gynecological examination, laboratory examination)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2010
Enrollment:	110
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ethinylestradiol / gestodene
Generic name:	Ethinylestradiol / gestodene

Ethics review

Approved WMO

Date:	10-09-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	13-09-2010
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	EUCTR2010-021255-81-NL
CCMO	NL33171.056.10
Other	not yet available