

# 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

Published: 10-09-2010

Last updated: 03-05-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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

2 - Multicenter, open-label, randomized study to evaluate inhibition of ovulation du ... 31-05-2025

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/m<sup>2</sup> and 1 group with BMI higher than 30 kg/m<sup>2</sup>).

## **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

Bayer Schering Pharma  
D - 13353 Berlin  
DE

### Scientific

Bayer

Bayer Schering Pharma  
D - 13353 Berlin  
DE

## 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