

Influence of Silexan on pharmacokinetics and hormonal activity in females taking oral contraceptives

Submission date 13/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/12/2009	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
750201.01.019

Study information

Scientific Title

Double-blind, placebo-controlled, randomised, cross-over study to evaluate the interacting influence of 160 mg Silexan (WS®1265) on pharmacokinetics, and hormonal and ovarian activity in 24 healthy females taking an oral contraceptive containing 0.03 mg ethinyl estradiol and 0.15 mg levonorgestrel

Study objectives

The objective of the study is to assess the interacting potential of 160 mg once daily administration of Silexan on the pharmacokinetics of ethinyl estradiol and levonorgestrel.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethik-Kommission des Landes Berlin approved on the 12th October 2009 (ref: ZS EK 12 432/09)

Study design

Single centre double-blind randomised placebo-controlled cross-over study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Pharmacokinetics of ethinyl estradiol and levonorgestrel

Interventions

One capsule with 160 mg Silexan or placebo respectively per day in the morning for 2 times 28 days (56 consecutive days).

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Ethinyl estradiol, levonorgestrel, Silexan (WS®1265)

Primary outcome measure

Plasma levonorgestrel and ethinyl estradiol: AUC_{tau}, at the PK profile days over 24 hours at day 19, 20 or 21 of the cycle.

Secondary outcome measures

1. Hoogland score assessments at day 28 of the cycle
2. C_{max} and t_{max} of levonorgestrel and ethinyl estradiol profiles, assessed over 24 hours at day 19, 20 or 21 of the cycle
3. Safety and tolerability

Overall study start date

01/12/2009

Completion date

31/05/2010

Eligibility**Key inclusion criteria**

1. Aged 18 - 38 years
2. Signed informed consent
3. Healthy female volunteer
4. Body mass index between 18 and 30 kg/m²
5. At least 3 months since delivery, abortion, or lactation before randomisation
6. Willingness to use non-hormonal methods of contraception
7. Subjects must have taken oral contraceptive for at least two cycles before start of the first treatment cycle

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

24

Key exclusion criteria

1. Pregnancy, a repeatedly positive urine pregnancy test or lactation
2. Known or suspected malign tumours or history thereof
3. Thrombophlebitis, venous or arterial thromboembolic diseases (thrombosis, pulmonary embolism, stroke or myocardial infarction) or other conditions that increase susceptibility to thromboembolic diseases
4. Known or suspected benign tumours of the liver, pituitary and adrenal gland or history thereof

5. Known or suspected liver disorders, diabetes mellitus, pancreatitis or a history thereof if associated with severe hypertriglyceridemia or disturbances of lipid metabolism, kidney disease with impaired renal function
6. Gastrointestinal disorders with uncertain absorption of orally administered drugs
7. Known allergy to lavender oil or other ingredients of the investigational drug
8. History of migraine with neurological symptoms
9. Clinically significant depression (current or during the last year)
10. Any known diseases or conditions that compromise the function of the body systems and could result in altered absorption, excessive accumulation, impaired metabolism, or altered excretion of the study medication
11. Any known severe systemic disease that might interfere with the conduct of the study or the interpretation of the results
12. Clinically relevant deviations from screened laboratory parameters
13. Sick-cell anaemia
14. Epilepsy
15. Alcohol, drug, or medicine abuse or suspicion thereof
16. Donation of blood or plasmapheresis after signing the informed consent
17. Regular intake of the following medication:
 - 17.1. Any drugs that might interfere with the study objectives especially any drugs known to induce liver enzymes
 - 17.2. Any drugs known to inhibit CYP3A4
 - 17.3. Any broad-spectrum antibiotics, long-acting injectable or implant hormonal therapy within 26 weeks prior to the screening phase
 - 17.4. Any continuous combined oral contraceptive (COC) intake regimen after screening

Date of first enrolment

01/12/2009

Date of final enrolment

31/05/2010

Locations

Countries of recruitment

Germany

Study participating centre

Anklamer Straße 38

Berlin

Germany

10115

Sponsor information

Organisation

Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Sponsor details

Willmar-Schwabe-Straße 4
Karlsruhe
Germany
76227

Sponsor type

Industry

ROR

<https://ror.org/043rrkc78>

Funder(s)**Funder type**

Industry

Funder Name

Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration