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

Submission date	Recruitment status	[ ] Prospectively registered
13/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/12/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2009	Other	[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Plasma levonorgestrel and ethinyl estradiol: AUCtau, at the PK profile days over 24 hours at day 19, 20 or 21 of the cycle.

Key secondary outcome(s))
1. Hoogland score assessments at day 28 of the cycle
2. Cmax and tmax of levonorgestrel and ethinyl estradiol profiles, assessed over 24 hours at day 19, 20 or 21 of the cycle
3. Safety and tolerability

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/m^2
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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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 hypertriglycidemia 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. Sickle-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)

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration