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Driving fitness under Silexan compared to placebo and lorazepam

Submission date
11/03/2016

Recruitment status
No longer recruiting

Registration date
30/03/2016

Overall study status
Completed

Last Edited
17/06/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Certain medical conditions and drugs can affect a person's ability to drive. Users of many medications are warned not to drive while taking them, especially in the case of anti-anxiety medications and antidepressants, which can make life difficult for some people. Silexan is a new German-developed lavender oil supplement which has been found to be very effective in the treatment of anxiety disorders. Previous studies have shown that there are no sedative effects of taking silexan, and so users could potentially still be able to drive while taking the medication. This study takes place in two parts. The first part of the study aims to investigate the effects of taking silexan on driving fitness (ability to drive) compared to a placebo (dummy pill). The second part of the study aims to investigate the effects of taking silexan on driving fitness compared to lorazepam (an anti-anxiety medication).

Who can participate?
Healthy adults aged between 25 and 60 who have held a driving license for at least three years.

What does the study involve?
In the first part of the study, 48 participants are randomly allocated to receive two treatments in a different order. The first treatment consists of taking 80mg silexan every day for eight days and the second treatment consists of taking an identical looking placebo (dummy pill) every day for eight days. Between the two treatments, participants have a 'wash-out' period (in which no medication in taken) for seven days. In the second part of the study, 24 participants are randomly allocated to receive four treatments in a different order: 160mg silexan, 320mg silexan, 1mg lorazepam and a placebo (dummy pill). Each of these treatments consists of taking five identical looking capsules (as a single dose). Between the two treatments, participants have a 'wash-out' period (in which no medication in taken) for seven days. The driving performance of the volunteers will be investigated using a test course in a driving simulator after the first and last dose In each treatment period for part one, and after each treatment in part two. Participants will be instructed to drive safely, accurately and quickly without violating the rules of the road and are observed in order to assess their performance.

What are the possible benefits and risks of participating?
There are no direct benefits to those taking part in the study besides receiving a comprehensive

medical examination. There is a small risk that participants may experience side effects from the medications, however they are both expected to be well tolerated.

Where is the study run from?
Medical Study Center Würzburg (Germany)

When is the study starting and how long is it expected to run for?
July 2015 to August 2017

Who is funding the study?
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2015-001101-14

Protocol serial number
750253.01.030

Study information

Scientific Title
Driving fitness under acute and subchronic application of Silexan® (WS® 1265) in comparison to placebo and Lorazepam with healthy volunteers in two successive, randomized, double-blind, crossover designed trial parts

Study objectives

Part one:
The aim of this study is to test the non-inferiority and equivalence of driving fitness after application of 80 mg Silexan in comparison to placebo.

Part two:
The aim of this study is to investigate the superiority of 160 mg and 320 mg Silexan with respect to driving fitness in comparison to 1.0 mg Lorazepam.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission der Bayerischen Landesärztekammer, 24/02/2016, ref: 15132

Study design
Part one:
Monocentric randomized double-blind placebo-controlled cross-over study with two treatments and two sequences

Part two
Monocentric randomized double-blind placebo- and reference-controlled cross-over part with four treatments and four sequences

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Driving fitness

Interventions
Part one:
Volunteers receive orally 80 mg Silexan (Lasea) and placebo in a two period cross-over design. They take one capsule once daily for 8 days followed by a wash out period of 7 days. In a second treatment period volunteers take one capsule once daily for 8 days.
Day 1: The Stanford Sleepiness Scale is measured before intake of the investigational product and before driving in the simulator. 90 min after intake of investigational product volunteers start a 60 min driving session in the driving simulator. While driving, a specially trained researcher will register subjects' driving errors and assess their driving performance on the 11-points-rating scale according to Neukum & Krüger. After driving, volunteers will rate their driving performance subjectively on the scale according to Neukum & Krüger.
Day 8: After 7 days of intake the same procedures as on Day 1 take place.
Day 15: After a washout period of one week, the same procedures as on Day 1 take place but with the other cross-over medication.
Day 22: Same as Day 8.

Part two:
Volunteers receive orally 160 mg and 320 mg Silexan (Lasea), 1.0 mg Lorazepam (Tavor) and placebo in a four period cross over design. They take five capsules as a single dose followed by a

wash our period of 7 days between the treatment periods.
Day 1: The Stanford Sleepiness Scale is measured before intake of the investigational product and before driving in the simulator. 90 min after intake of investigational product volunteers start a 60 min driving session in the driving simulator. While driving, a specially trained researcher will register subjects' driving errors and assess their driving performance on the 11-points-rating scale according to Neukum & Krüger. After driving, volunteers will rate their driving performance subjectively on the scale according to Neukum & Krüger.
Day 8: After a washout period of one week, the same procedures as on Day 1 take place but with the second cross-over medication.
Day 15: After a washout period of one week, the same procedures as on Day 1 take place but with the third cross-over medication.
Day 22: After a washout period of one week, the same procedures as on Day 1 take place but with the fourth cross-over medication.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Silexan

Primary outcome(s)
Standard deviation of lane position during the vigilance section is measured in centimeters at the driving simulator after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2 (for both parts: day 1, day 8, day 15 and day 22).

Key secondary outcome(s))
1. Rater's global assessment of subjects' driving performance is measured using the Fitness-to-Drive-Scale at the driving simulator after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2
2. Number of driving errors in total and in subcategories (tactical errors with respect to longitudinal control, operational errors with respect to lateral control, cognitively based errors, number of collisions and critical situations) is measured at the driving simulator after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2
3. Driving performance is measured on the Fitness-to-Drive-Scale through a subjective assessment after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2
4. Sleepiness is measured using the Eyelid Closure Index in the vigilance section at the driving simulator after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2
5. Reaction time to sudden events is recorded at the driving simulator after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2
6. Subjective sleepiness is measured using the Stanford Sleepiness Scale after the first and the last dose in both treatment periods in part 1 and after the single dose in each of the four treatment periods in part 2
7. Adverse events (serious) are asked by the investigator at every visit

Completion date
30/08/2017

Eligibility

Key inclusion criteria
1. Aged 25 to 60 years
2. Active drivers that have had a driver's license for at least 3 years and have a minimal mileage per year of 3000 km
3. Written informed consent
4. Only for female volunteers who have not entered menopause and who are not sterilized: Using a highly effective method of birth control that has a very low failure rate

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
201

Key exclusion criteria
1. Participation in another clinical trial at the same time or within the past 4 weeks before enrolment
2. Acute illness and/or infections and/or fever within the past 7 days prior to administration of IMP
3. Increased intraocular pressure
4. Chronic illness
5. Gastrointestinal disorders with uncertain absorption of orally administered drugs
6. < 3 months before inclusion of the participant: use of psychoactive substances
7. < 2 weeks before inclusion of the participant: use of centrally acting drugs
8. < 3 months before inclusion of the participant: use of recreational drugs, e.g. CNS stimulants like amphetamines, cannabis, cocaine and others
9. History or evidence of alcohol or drug abuse/dependence
10. Positive result in the drug screening or in the alcohol breath test at screening visit
11. Presence or history of clinically relevant allergy or a known or suspected hypersensitivity to lavender oil, Lorazepam and/or excipients of the IMP or benzodiazepines
12. Any clinically relevant laboratory value which the investigator decides might affect the study objectives
13. Females who are breastfeeding or who are pregnant

Date of first enrolment
29/03/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Germany

Study participating centre
Medical Study Center Würzburg (Medizinisches Studienzentrum Würzburg)
Augustinerstraße 15
Würzburg
Germany
97070

Sponsor information

Organisation
Dr. Willmar Schwabe GmbH & Co. KG

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr. Willmar Schwabe GmbH & Co. KG

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			17/06/2020	No	No