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Effects of Silexan on brain function and brain structure

Submission date	Recruitment status	[_] Prospectively registered
12/07/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2015	Nervous System Diseases	

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
750201.01.029

Study information

Scientific Title

Effects of Silexan (WS® 1265) on the serotonin-1A (5-HT1A) receptor and microstructure of the brain: a randomized, placebo-controlled, double-blind, cross-over study with molecular and structural neuroimaging

Study objectives
The objective of the study is to detect effects of an at least eight-week treatment with Silexan (WS® 1265) on the serotonergic system and the microstructure of the brain via molecular and structural neuroimaging.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Vienna (Ethik-Kommission des Medizinischen Universität Wien), 11/07/2011, ref: 475/2011

Study design
Single-centre randomized placebo-controlled double-blind cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

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
Brain function

Interventions
1. The volunteers take 1 x 2 capsules orally in the morning for eight weeks followed by a wash out phase without treatment of 2-3 weeks followed by a second treatment period of eight weeks
2. The randomized order of the two eight-weeks-periods is Silexan - placebo or placebo - Silexan
3. The dosage of a capsule with Silexan is 80 mg

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Silexan (WS® 1265)

Primary outcome measure
1. Regional 5-HT1A receptor binding potential of the brain after at least 8 weeks of Silexan (WS® 1265) treatment as compared to placebo (positron emission tomography [PET] scan data)
2. Regional brain grey matter density and volume after at least 8 weeks of Silexan (WS®1265) treatment as compared to placebo (magnetic resonance imaging [MRI] scan data)

Secondary outcome measures
1. Physical examination
2. Vital signs
3. Adverse events
4. Laboratory tests

Overall study start date
01/08/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Age 20 - 50 years
2. Male
3. Caucasian
4. Informed consent
4. Healthy
5. Body mass index between 18 and 29.9 kg/m²

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
18

Key exclusion criteria
1. Subjects with depression or comorbid axis I diagnoses
2. Subjects who are not naive to psychotropic drug treatment targeting the serotonergic system
3. Blood donation of approximately 500 ml within 3 months prior to the study start
4. A history of relevant diseases of vital organs, of the central nervous system or other organs

5. Subjects with a medical disorder, condition or history of such that would impair the subject's ability to participate or complete this study
6. Febrile illness within 1 week before the start of the study
7. Subjects with a history of severe allergies, non-allergic drug reactions, or multiple drug allergies
8. Regular daily consumption of more than ½ liter of regular beer or the equivalent quantity of approximately 20g of alcohol in another form
9. Regular daily consumption of more than 10 cigarettes
10. Regular use of therapeutic or recreational drugs
11. Subjects with known hypersensitivity to essential oils
12. Use of medication within the 2 weeks preceding the study which could interfere with the investigational product; chemistry
13. Resting heart rate in the awake subject below 45 BPM or above 90 BPM
14. Systolic blood pressure below 100 mmHg or above 140 mmHg
15. Diastolic blood pressure above 85 mmHg
16. Subjects testing positive in the drug screening

Date of first enrolment
01/08/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Austria

Study participating centre
Währinger Gürtel 18-20
Vienna
Austria
1090

Sponsor information

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

Sponsor details
c/o Mr Stephan Klement
Willmar-Schwabe-Straße 4
Karlsruhe
Germany
76227

Sponsor type
Industry

Website
http://www.schwabepharma.com/international/

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Willmar Schwabe GmbH and 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/10/2014		Yes	No