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Effects of Sokatin® on emotional memory and set shifting

Submission date	Recruitment status	[ ] Prospectively registered
25/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/09/2011	Mental and Behavioural Disorders	[ ] 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
750402.01.020

Study information

Scientific Title
A phase I study to assess the effects of repeated oral doses of Sokatin® (WS® 1261) for 2 weeks on emotional memory and set shifting in healthy volunteers

Study objectives
The objective of this clinical trial is to describe the influence of a two weeks treatment with Sokatin® (WS® 1261) on emotional memory and set shifting as well as working memory

measured with functional magnetic resonance imaging and with a battery of psychometric test scales in healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik Kommission des Landes Berlin approved on the 8th December 2009 (ref: ZS EK 15 533/09)

Study design
Single centre double-blind randomised placebo-controlled cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Emotional memory and set shifting

Interventions
1 tablet containing 500 mg Sokatin® or placebo taken in the morning.

Schedule:
Screening phase: up to 14 days
Treatment period 1: verum or placebo for 14 days once daily
Wash-out period: 14 days
Treatment period 2: placebo or verum for 14 days once daily
Total duration after baseline: day 1 to day 43

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Sokatin® (WS® 1261)

Primary outcome(s)
Memory tasks and set shifting measured with functional magnetic resonance imaging. Measured at day 15 (after treatment period 1) and day 43 (after treatment period 2) (no baseline measures for fMRI).

Key secondary outcome(s))
1. Psychometric testing with standardised questionnaires (Wisconsin Card Sorting test, emotional stroop test, Beck Depression Inventory [BDI], Social Adaptation Self-evaluation Scale [SASS], Cognitive Dissonance Test [DISS], Befindlichkeits Skala [Mood Scale, BF-S], Beschwerden

Liste [Complaint List, B-L], Eigenschaftswörterliste [Adjective Checklist, EWL-60], 36-item short form health survey [SF-36], Quality of Life Enjoyment and Satisfaction Questionnaire [QLES-Q])
2. Safety and tolerability

Measured at day 1, day 15, day 29 and day 43.

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Aged 20 - 30 years
2. Male
3. Caucasian
4. Informed consent in accordance with the legal requirements
5. Healthy
6. Normal body weight

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Subjects with conspicuous findings in medical history and pre-study examination
2. Blood donation of approximately 500 ml within 3 months prior to the study start
3. A history of relevant diseases of vital organs, of the central nervous system or other organs
4. Subjects with a medical disorder, condition or history of such that would impair the subject's ability to participate or complete this study in the opinion of the investigator or the sponsor
5. Febrile illness within 1 week before the start of the study
6. Subjects with a history of severe allergies, non-allergic drug reactions, or multiple drug allergies
7. Regular daily consumption of more than 10 cigarettes
8. Regular daily consumption of more than half a litre of usual beer or the equivalent quantity of approximately 20 g of alcohol in another form
9. Regular use of therapeutic or recreational drugs
10. Use of medication within the 2 weeks preceding the study which could interfere with the investigational product
11. Relevant deviation from the normal range in the clinical examination
12. Relevant deviation from the normal range in clinical chemistry, haematology or urinalysis
13. Resting heart rate in the awake subject below 45 beats per minute (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
17. Excluded therapies (e.g., physiotherapy, acupuncture, etc)
18. Gastrointestinal disorders with uncertain absorption of orally administered drugs
19. Volunteer in custody or submitted to an institution due to a judicial order
20. Contraindications for magnetic resonance imaging: metallic implants (including non-removable body piercing), large tattoos, medical or biostimulation implants such as pacemaker, claustrophobia, allergy to the contrast agent

Date of first enrolment
01/03/2010

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
Germany

Study participating centre
Eschenallee 3
Berlin
Germany
14050

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