ISRCTN59780402 https://doi.org/10.1186/ISRCTN59780402

The effects of Sokatin® on mood and cognitive function

Submission date	Recruitment status	[ ] Prospectively registered
22/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/12/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/12/2010	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
750402.01.028

Study information

Scientific Title
The effects of Sokatin® on mood and cognitive function: a double-blind, placebo-controlled, randomised cross-over study

Study objectives
To investigate if daily oral intake of 500 mg Sokatin® improves mood and cognitive function in healthy subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research Subjects and Patients Medical Ethical Review (Medisch-Ethische Toetsing Onderzoek Patienten en Proefpersonen [METOPP]) approved on the 20th October 2010 (ref: M375; NL 33836.028.10)

Primary study design
Interventional

Study design
Explorative randomised double blind placebo controlled crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mood/cognitive function

Interventions
Daily intake of one tablet Sokatin® for a period of eight weeks (test) or daily intake of one placebo tablet for a period of eight weeks (control) and vice versa with a wash-out period of 2 weeks in between.

Intervention Type
Drug

Phase
Phase I/II

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

Primary outcome(s)
1. Cognitive performance:
1.1. Emotional Stroop Test
1.2. Colour Word Vigilance Test
1.3. N-back Test
1.4. Vigilance and Tracking Test
1.5. Switching Attention Test
1.6. Long-term Memory Task
2. Profile of Mood States Questionnaire

The assessment of mood and cognitive performance using the selected cognitive tests of a computerised validated test system are performed on day 01, day 57, day 71 and day 127.

Key secondary outcome(s)
No secondary outcome measures

Completion date
28/02/2011

Eligibility

Key inclusion criteria
1. Healthy volunteers (male and female) aged 30 to 50 years
2. Able to perform easy actions on a computer
3. Candidates with scores greater than or equal to 45 in the State-Trait Anxiety Inventory (STAI-T) during screening
4. Having given written informed consent
5. Willing to comply with the study procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation in any clinical trial up to 90 days before Day 01 of this study
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study
3. Having a history of medical or surgical events that may significantly affect the study outcome, including psychiatric disorders
4. Being colour-blind
5. Use of antidepressants
6. Being hypersensitive to any ingredient of the study substances
7. Use of supplements from screening towards the end of the study
8. Being a regular user of recreational drugs
9. Excessive alcohol consumption or excessive use of tobacco
10. Reported slimming or medically prescribed diet
11. Pregnant or lactating or wishing to become pregnant in the period of the study
12. Not having a general practitioner

Date of first enrolment
25/10/2010

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Utrechtseweg 48
Zeist
Netherlands
3700

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