

# The effects of Sokatin® on mood and cognitive function

<b>Submission date</b> 22/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/12/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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)

## **Study design**

Explorative randomised double blind placebo controlled crossover study

## **Primary study design**

Interventional

## **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