

# Influence of Sokatin® on parameters of the mental and psychic function

<b>Submission date</b> 08/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2010	<b>Condition category</b> Signs and Symptoms	<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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Germany  
30167

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
750402.01.026

## Study information

**Scientific Title**

Influence of Sokatin® on parameters of the mental and psychic function: An open label, explorative study

### **Study objectives**

The objective of the study is to assess the influence of Sokatin on the mental and psychic efficiency in volunteers with mild symptoms of exhaustion or fatigue

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Freiburg Ethics Committee (Freiburger Ethik-Kommission) approved on the 10th of May 2010 (ref: 010/1763)

### **Study design**

Single centre open explorative study

### **Primary study design**

Interventional

### **Secondary study design**

Cohort study

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Condition: mild symptoms of exhaustion or fatigue

### **Interventions**

One tablet of 500 mg Sokatin® per day in the morning for eight weeks.  
The intake phase will be eight weeks.

### **Intervention Type**

Drug

### **Phase**

Phase II

### **Drug/device/biological/vaccine name(s)**

Sokatin®

### **Primary outcome measure**

1. Numerical Analogue Scales: motivation, concentration, exhaustion, resilience and somatic symptoms, measured at baseline, day 7 and weeks 4 and 8
2. Multidimensional Fatigue Inventory 20, measured at baseline, day 7 and weeks 4 and 8
3. Global Self-rating of Efficacy, measured at baseline, day 7 and weeks 4 and 8
4. SF-36 Health Survey, assessed at weeks 4 and 8
5. Sheehan Disability Scale, measured at baseline, day 7 and weeks 4 and 8
6. Fatigue Impact Scale, assessed at weeks 4 and 8

### **Secondary outcome measures**

None

### **Overall study start date**

15/06/2010

### **Completion date**

31/12/2010

## **Eligibility**

### **Key inclusion criteria**

1. Male and female caucasians aged 30 to 60 years
2. Written informed consent
3. Readiness, and ability on the part of the subject to comply with the physicians instructions
4. At least 3 of the symptoms listed below assessed as > 5 on NASs:
  - 4.1. motivation
  - 4.2. concentration
  - 4.3. exhaustion
  - 4.4. resilience
  - 4.5. somatic symptoms

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

50

### **Key exclusion criteria**

1. Concomitant medications:
  - 1.1. Antidepressives
  - 1.2. Supplements with ingredients of the test substance
  - 1.3. Corticosteroids
  - 1.4. Immunosuppressive agents
  - 1.5. Non-steroidal anti-inflammatory agents (NSAIDs) within one month before study start
  - 1.6. Antibiotics within one month before study start

- 1.7. Vitamin and mineral nutrients supplement in dosages considerable above the recommended daily allowance
- 1.8. Laxatives (regular)
2. Diagnosed disease considered as cause of exhaustion or fatigue:
  - 2.1. Chronic infectious diseases
  - 2.2 Immune mediated diseases
  - 2.3. Myasthenia
  - 2.4. Neurological diseases
  - 2.5. Cardio respiratory diseases
  - 2.6. Metabolic diseases
  - 2.7. Psychiatric diseases
  - 2.8. Severe sleep disorder
3. Other diseases:
  - 3.1. Severe chronic diseases
  - 3.2. Apparent cardio vascular disease
  - 3.3. Renal insufficiency
  - 3.4. Liver diseases
  - 3.5. Chronic disorders of the gastro-intestinal tract
  - 3.6. Heart surgery
  - 3.7. Surgery on digestive tract
  - 3.8. Planned surgery
4. Pregnancy and lactation
5. Alcohol and/or substance abuse or dependence
6. Participation in another experimental trial at the same time or within the past 30 days before enrolment
7. Known hypersensitivity to ingredients of the test substance

**Date of first enrolment**

15/06/2010

**Date of final enrolment**

31/12/2010

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

**Am Kleinen Felde 30**

Hannover

Germany

30167

## **Sponsor information**

**Organisation**

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

**Sponsor details**

Willmar-Schwabe-Straße 4  
Karlsruhe  
Germany  
76227

**Sponsor type**

Industry

**ROR**

<https://ror.org/043rrkc78>

**Funder(s)****Funder type**

Industry

**Funder Name**

Dr. Willmar Schwabe GmbH & 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