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

Submission date 08/06/2010	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 19/07/2010	Overall study status Completed	Statistical analysis plan
		☐ Results
Last Edited	Condition category	Individual participant data
19/07/2010	Signs and Symptoms	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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Contact details

Am Kleinen Felde 30 Hannover 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