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

Submission date 08/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/07/2010	**Overall study status** Completed	
Last Edited 19/07/2010	**Condition category** Signs and Symptoms	

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
750402.01.026

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)

Primary study design
Interventional

Study design
Single centre open explorative study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
None

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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