The effects of Sokatin® on mood and cognitive function

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The objective of the study is to investigate if daily oral intake of 500 mg Sokatin® improves mood and cognitive function in healthy subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34482

Source
ToetsingOnline

Brief title
Sokatin®, mood and cognition

Condition

- Other condition

Synonym
state of mind and mental capacity

Health condition

stemming en cognitief functioneren (met name geheugen en concentratie)

Research involving
Human

Sponsors and support

Primary sponsor: Dr. Willmar Schwabe GmbH & Co. KG
Source(s) of monetary or material Support: Dr. Willmar Schwabe GmbH & Co. KG

Intervention

Keyword: cognition, flavonoids, mood, Opuntia ficus indica

Outcome measures

Primary outcome

Assessment of mood and cognitive performance using selected cognitive tests of

a computerized validated test system.

Secondary outcome

Assesment of mood by means of a Profile of Mood States questionnaire (POMS-32)

that has to be filled in by the subjects once weekly.

Study description

Background summary

In several countries all over the world the different parts of Opuntia species (i.e. cactus) are appreciated as a traditional and valuable food and medicine. The genus Opuntia included about 200 species, of which Opuntia ficus indica has the greatest economic importance. Sokatin® is an extract from the flowers of Opuntia developed by Dr. Willmar Schwabe GmbH & Co. KG. Results of animal studies suggest that mood or anxiety, memory and learning function may be positively affected after intake of Sokatin®. Taking into account the main active ingredient of Sokatin®, isorhamnetin, in particular (antioxidant) effects on age-related decline of memory may be expected.

Study objective

The objective of the study is to investigate if daily oral intake of 500 mg Sokatin® improves mood and cognitive function in healthy subjects.

Study design

The study is designed as an explorative, randomized, double-blind, placebo-controlled, crossover study.

Intervention

The treatments consist of 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. Tablets have to be taken 30 to 60 minutes before breakfast.

Study burden and risks

The following burden may be experienced:
1. Blood sampling for the screening (once)
2. Filling in 2 questionnaires for screening (Health and Lifestyle questionnaire and Anxiety scores in the STAI)
3. Visit to TNO: once for screening, 6x in study
4. Daily intake of a tablet; * to 1 h before breakfast during 16 weeks
5. Daily filling in a diary during 16 weeks
6. 4x performance of computertests
7. 6x filling in questionnaire on wellbeing
8. Weekly filling in a questionnaire on mood state (POMS)

Subjects will have their own habitual meals at home. Subjects are asked to maintain their habitual diets. However, subjects are asked not to exceed the amounts of fruits, vegetables and alcohol consumption as indicated by the Dutch Food Guidelines (i.e. 200 g of vegetables and 2 portions of fruit per day, 1 glass of alcohol per day for women, 2 glasses of alcohol per day for men).

Restrictions with respect to the test days are the following:
-Good night rest the night prior to the test day;
-No alcoholic beverages the day before the test day;
-Maintain habitual coffee intake, but intake should be the same (in amount of cups of coffee) on all the days before the test days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Healthy as assessed by the
- health and lifestyle questionnaire
- results of the pre-study laboratory tests in blood
2. Males and females aged between 30 and 50 years at Day 01 of the study
3. Able to perform easy actions on a computer
4. Having a score >= 45 in the STAI-T at screening
5. Voluntary participation
6. Having given written informed consent
7. Willing to comply with the study procedures
8. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
9. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

1.Participation in any clinical trial including blood sampling and/or administration of substances 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, including no blood sampling and/or oral, intravenous, inhalatory administration of substances
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. Alcohol consumption > 28 units/week for males and > 21 units/week for females
10. Excessive smoking (> 20 cigarettes per day)
11. Reported slimming or medically prescribed diet
12. Pregnant or lactating or wishing to become pregnant in the period of the study
13. Personnel of TNO Quality of Life, their partner and their first and second degree relatives
14. Not having a general practitioner
15. Not willing to accept information-transfer concerning participation in the study to your general practinioner
16. Not willing to accept information-transfer concerning your health, like laboratory results, findings at anamnesis and eventual adverse events to and from your general practitioner.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2010
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	30-11-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33836.028.10