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The effect of Rhodiola rosea Extract WS 1375 on attention and mental resource allocation

Submission date	Recruitment status	[X] Prospectively registered
16/02/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/03/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/05/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rhodiola rosea is a traditional herbal medicine. The aim of this study is to look at the possible influence of Rhodiola rosea Extract WS® 1375 on visual attention and mental resource allocation in healthy volunteers at risk of stress.

Who can participate?
Healthy volunteers aged 30 to 50 who work on a computer for at least 15 hours per week

What does the study involve?
All participants take Rhodiola rosea Extract WS 1375 orally for 12 weeks and its effects on attention and dual task performance are assessed.

What are the possible benefits and risks of participating?
Rhodiola rosea extract may relieve symptoms associated with stress such as fatigue and exhaustion, and improve physical and mental work capacities under stressful conditions. There are no reported side effects related to Rhodiola rosea extract.

Where is the study run from?
Universitätsklinikum Schleswig-Holstein (Germany)

When is the study starting and how long is it expected to run for?
March 2012 to July 2013

Who is funding the study?
Dr Willmar Schwabe GmbH & Co. KG (Germany)

Who is the main contact?
Prof. Thomas Münte

Contact information

Type(s)

Scientific

Contact name
Prof Thomas Münte

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
578001.01.019

Study information

Scientific Title
Single center, open-label clinical trial to study the effects of Rhodiola rosea extract WS 1375 on neuropsychological and neurophysiological measures of attention and mental resource allocation in healthy volunteers

Study objectives
To gain initial insight in the possible influence of Rhodiola rosea extract WS 1375 on visual attention and mental resource allocation in healthy subjects at risk for stress symptomatology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Association of Schleswig-Holstein [Ethik Kommission des Universitätsklinikums Schleswig-Holstein], 14/02/2012, ref: 11-244

Study design
Single-center open-label exploratory trial

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Neuropsychological and neurophysiological measures

Interventions
One treatment arm only - Rhodiola rosea Extract WS 1375 (2 x 200mg) administered orally for 12 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Attention Network Task
2. Go/NoGo Test
3. Divided Attention Test
4. Number Connection Test
5. Beck Depression Inventory II
6. Recent Perceived Stress Questionnaire
7. Event-related potentials

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/03/2012

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Healthy male or female volunteers aged 30 to 50 years (both inclusive)
2. Signed Informed consent in accordance with the legal requirements
3. Sufficient language skills, readiness, and ability on the part of the subject to comply with the physicians instructions, respond to all interview questions, and to fill in the self-assessment

scales without evident difficulties and without the assistance of an interpreter
4. Participants are required to work with a computer at least 15 hrs per week
5. Self-report of occasional visual and mental fatigue during computer work (scores 5 on at least 3 questions of the Ermdung und Computerarbeit questionnaire)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
50 subjects eligible for treatment

Key exclusion criteria
1. Participation in another experimental drug trial at the same time or within the past 12 weeks before enrollment
2. Current hospitalization of the subject
3. Any clinically significant disease
4. Risk of suicide
5. History or evidence of alcohol and/or substance abuse or dependence, particularly of sedatives, hypnotics and anxiolytics within the last 5 years
6. History of Axis I disorders according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV) at least one year before enrollment
7. History of head trauma that might be causally related to cognitive impairment
8. Non-medical psychiatric treatment (e.g., specific standardized psychotherapy) at least 4 weeks before the study
9. Unacceptability to discontinue or likelihood to need medication during the study that is prohibited as concomitant treatment
10. Any clinically relevant hepatic, renal (serum creatinine or serum ASAT, ALAT or Gamma GT above 3 times the upper limit of the reference range), cardiovascular, respiratory, cerebrovascular, metabolic disorder or progressive diseases as cancer (exception: prostate cancer T1N0M0 which does not require treatment within the next 7 months except hormone therapy), haematologic diseases or thyroid insufficiency, epilepsy or a history of seizure disorder or treatment with anticonvulsants for epilepsy or seizures, Parkinson's disease, diabetes mellitus
11. Any acute or chronic form of infection including Human immunodeficiency virus (HIV) infection or Lues of any stage (according to medical history or clinical signs and symptoms)
12. Known hypersensitivity to Rhodiola rosea extract
13. Gastrointestinal disorders with uncertain absorption of orally administered drugs (e.g. partial or total gastrectomy, enterectomy, inflammatory bowel disease, celiac disease, symptomatic lactose intolerance, other disorders associated with chronic diarrhoea)
14. Pregnancy, lactation
15. Women capable of childbearing if not using adequate contraception (intra-uterine devices, injectable contraception, oral contraceptives plus one other contraceptive measure)
16.Score of 14 or higher on Beck Depression Inventory II (BDI II)

Date of first enrolment
15/03/2012

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Schleswig-Holstein
Lübeck
Germany
23538

Sponsor information

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

Sponsor details
Willmar Schwabe Str. 4
Karlsruhe
Germany
76227

Sponsor type
Industry

Website
http://www.schwabepharma.com/

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