

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

Submission date 16/02/2012	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 05/03/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 26/05/2017	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ 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

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Single-center open-label exploratory trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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