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Rhodiola rosea Extract WS® 1375 in subjects with chronic fatigue symptoms

Submission date
07/02/2012

Recruitment status
No longer recruiting

Registration date
12/03/2012

Overall study status
Completed

Last Edited
08/08/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Clinical studies and experiments with Rhodiola rosea extract have demonstrated significant relief of stress, fatigue and exhaustion. The aim of this study is to obtain information about the effects and safety of Rhodiola rosea extract in subjects with chronic fatigue symptoms.

Who can participate?
Male or female outpatients aged 18 to 60 years with clinically evaluated, unexplained persistent or relapsing fatigue symptoms lasting for at least 2 months.

What does the study involve?
Participants will undergo a physical examination, electrocardiogram (ECG) and laboratory tests including blood sampling at the beginning and the end of the trial. All participants will be treated with Rhodiola rosea extract. We will measure the effects of treatment on fatigue, sleep, concentration and level of activity.

What are the possible benefits and risks of participating?
Published clinical studies reported no adverse events for participants under active treatment related to Rhodiola rosea extract.

Where is the study run from?
The study is running in 10 sites/university based clinics in Ukraine.

When is the study starting and how long is it expected to run for?
The study ran from December 2011 to August 2012.

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
578001.01.011

Study information

Scientific Title
Rhodiola rosea Extract WS® 1375 in subjects with chronic fatigue symptoms

Study objectives
The objective of this clinical trial is to describe therapy effects, safety and tolerability of Rhodiola rosea Extract WS® 1375 in subjects with chronic fatigue symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethics Committee, Ministry of Health Ukraine, 05/07/2011, ref: 5.12-753/KE dtd

Study design
Open multicentre single-arm phase III study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic fatigue symptoms

Interventions
2 x 200 mg Rhodiola rosea Extract WS® 1375

The following self-rating scales and questionnaires will be used in this trial:
1. Multidimensional Fatigue Inventory 20 (MFI-20) assessment of the chronic fatigue symptoms
2. Three Numerical Analogue Scales of chronic fatigue symptoms (postexertional malaise, impaired memory and concentration; unrefreshing sleep)
3. Sheehan Disability Scale assessment of the impairment of daily living and reduction in previous levels of activity
4. Number Connecting Test assessment of memory and concentration
5. Pittsburgh Sleep Quality Index (PSQI) assessment of sleep quality
6. Recent Perceived Stress Questionnaire (PSQ-R) assessment of stress level
7. Becks Depression Inventory (BDI-II) assessment of depression
8. Clinical Global Impression (CGI) - physician rated, for changes from baseline as well as as for the assessment of the tolerability

The completion of the patient self-rating scales, including the NCT test with the stop watch will take estimated between 40 and 60 minutes per study visit. Not for all visits all test are required, in this case the estimated time for the completion of the questionnaires will be shorter, about 30 minutes.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Treatment effect outcome variables:
1. Multidimensional Fatigue Inventory 20 (MFI-20)
2. Three NASs of Chronic Fatigue Symptoms
3. Pittsburgh Sleep Quality Index (PSQI)
4. Numbers Connecting Test
5. Sheehan Disability Scale
6. Recent Perceived Stress Questionnaire (R-PS Qustionnaire)
7. Becks Depression Inventory (BDI-II)
8. Clinical Global Impressions (CGI)

Safety outcome variables:
1. Physical examination
2. Vital signs
3. Adverse events
4. Laboratory tests

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/08/2012

Eligibility

Key inclusion criteria

1. Male or female outpatients aged 18 to 60 years (both inclusive)
2. Signed Informed consent in accordance with the legal requirements
3. Clinically evaluated, unexplained persistent or relapsing fatigue symptoms lasted at least 2 months that:
3.1. Is not the result of ongoing exertion
3.2. Is not substantially relieved by rest
3.3. Results in substantial reduction in previous levels of occupational, educational, social or personal activities
4. The following perceived Chronic Fatigue Symptoms listed below assessed as ≥5 on NASs:
4.1. Postexertional malaise (extreme prolonged exhaustion following physical or mental exertion) lasting more than 24 hours
4.2. Substantial impairment in short-time memory and concentration
4.3. Unrefreshing sleep
5. Multidimensional Fatigue Inventory 20 (MFI-20) score 7 or more for the sub-scales:
5.1. General fatigue
5.2. Physical fatigue
5.3. Mental fatigue
6. Sufficient language skills, readiness, and ability on the part of the patient 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.
7. Negative pregnancy test at Screening visit in females of childbearing potential (non-childbearing potential is defined as post-menopause for at least one year or surgical sterilization or hysterectomy at least three months before study start).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Participation in another experimental drug trial at the same time or within the past 12 weeks before enrolment
2. Current hospitalization of the patient
3. Becks Depression Inventory (BDI-II) item 9 ≥ 1
4. History or evidence of alcohol and/or substance abuse or dependence, particularly of sedatives, hypnotics and anxiolytics within the last 5 years
5. History of Axis I disorders according to DSM-IV at least one year before enrolment - the last episode must have been finished at least one year before enrolment. (Common Axis I disorders include major depression, anxiety disorders, bipolar disorder, ADHD, autism spectrum disorders, phobias, and schizophrenia. Major Depression is defined by BDI-II total score >19 at Screening.)
6. Non-medical psychiatric treatment (e.g., specific standardized psychotherapy) at least 4 weeks

before the study.
7. Unacceptability to discontinue or likelihood to need medication during the study that is prohibited as concomitant treatment (specified in section 6). The following medication is not allowed during the study:
7.1. Any psychotropic drugs including CNS stimulants, tranquilizers / hypnotics (e.g. benzodiazepines, non-benzodiazepines like zopiclone or zolpidem, barbiturates), neuroleptics / antipsychotics, antidepressives, antiepileptics, antihistaminics, anti-emetics and nootropics
7.2. Long-term prophylactic treatment (e.g. lithium, carbamazepine)
7.3. Treatments for neuro-degenerative diseases
7.4. Central-acting antihypertensive medication (e.g. reserpine, clonidin, methyldopa), antihypertensive medication with guanethidine, guanoxan, prazosine
7.5. Beta-blockers (exception: stable dosage for at least 4 weeks)
7.6. Antiparkinson medication
7.7. Muscle relaxants
7.8. Analgetics of opiate type
7.9. Anesthetics
8. Clinical significant abnormality of ECG and/or laboratory value(s).
9. Any clinically relevant:
9.1. Hepatic, renal disorders (serum creatinine or serum ASAT, ALAT or Gamma GT above 3 times the upper limit of the reference range)
9.2. Cardiovascular diseases
9.3. Respiratory diseases
9.4. Metabolic disorder or progressive diseases as cancer (exception: prostate cancer T1N0M0 which does not require treatment within the next 7 months except hormone therapy)
9.5. Haematologic diseases
9.6. Cerebrovascular and neurologic diseases (epilepsy or a history of seizure disorder or treatment with anticonvulsants for epilepsy or seizures, Parkinsons disease, multiple sclerosis, injury with residual neurologic deficits)
10. Any form of diabetes mellitus
11. Clinically significant anaemia
12. Clinically significant thyroid dysfunction as expressed by significant abnormality in TSH, T3 and/or T4 levels
13. Any acute or chronic form of infection including HIV infection or Lues of any stage (according to medical history or clinical signs and symptoms).
14. Known hypersensitivity to Rhodiola rosea extract.
15. 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)
16. Pregnancy, lactation
17. Patients capable of childbearing if not using adequate contraception (intra-uterine devices, oral or injectable contraception)

Date of first enrolment
15/12/2011

Date of final enrolment
31/08/2012

Locations

Countries of recruitment

Germany

Ukraine

Study participating centre
Dr. Willmar Schwabe GmbH & Co. KG
Karlsruhe
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Sponsor information

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

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Research organisation

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