

Evaluating the efficacy and safety of Rhodiola rosea extract WS® 1375 in patients with burnout symptoms

Submission date 12/04/2011	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 22/06/2011	Overall study status Completed	☐ Protocol
Last Edited 22/06/2011	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Siegfried Kasper

Contact details

Universitätsklinik für Psychiatrie und Psychotherapie
Medizinische Universität Wien, AKH
Währinger Gürtel 18-20
Wien
Austria
1090

Additional identifiers

Protocol serial number

578001.01.012

Study information

Scientific Title

Multi-centre, open-label clinical trial to evaluate the efficacy and safety of Rhodiola rosea extract WS® 1375 in patients with burnout symptoms

Study objectives

Evaluation of the clinical efficacy of Rhodiola rosea extract WS® 1375 to treat burnout symptoms and improve quality of life, mood, concentration and general health

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical University of Vienna (Ethikkommission der Medizinischen Universität Wien und des AKH) approved on 31st May 2011 ref: EK-No 348/2011

Study design

Multi-centre open-label single arm trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Burnout symptoms

Interventions

Treatment with Rhodiola rosea extract WS® 1375, 2 x 200 mg/day

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Rhodiola rosea extract WS® 1375

Primary outcome(s)

1. Maslach Burnout Inventory (MBI)
2. Burnout-Screening-Scales BOSS I and BOSS II
3. Seven Numerical Analogue Scales of subjective stress symptoms (NAS)
4. Subjects perceived stress level: 30 items Recent Perceived Stress Questionnaire (PSQ)
5. Numbers Connecting Test
6. Sheehan Disability Scale (SDS)
7. Multidimensional Mood State Questionnaire (MDMQ)
8. NAS for Impairment of Sexual Life and Patient's Sexual Function Questionnaire (PSFQ)
9. Clinical Global Impressions (CGI)

Key secondary outcome(s))

No secondary outcome measures

Completion date

Eligibility

Key inclusion criteria

1. Male or female outpatient employed subjects (police officers and other officers, nurses, physicians, IT specialists etc.) and subjects with other comparable burdens (e.g home caring of handicapped or demented family members) aged 30 to 60 years (both inclusive)
2. Signed Informed consent in accordance with the legal requirements
3. Moderate level of burnout for the following dimensions of the Maslach-Burnout Inventory (MBI):
 - 3.1. Emotional exhaustion: level 1.81 2.80
 - 3.2. Reduced personal performance: level 3.90 4.79
4. At least three of perceived Life Stress Symptoms listed below assessed between 5 and 8 on Negative Affectivity Scale (NAS):
 - 4.1. Somatic symptoms: gastrointestinal or cardio-vascular disturbances, muscle tension or backache, frequent headaches
 - 4.2. Loss of zest for life
 - 4.3. Exhaustion
 - 4.4. Irritability (exploding easily at seemingly inconsequential things)
 - 4.5. Impairment of concentration
 - 4.6. Feeling of heteronomy
 - 4.7. Anxiety
5. Clinical Global Impression (CGI) Item 1: Score <4 at baseline
6. A level of >5 on the NAS for impairment of sexual life
7. 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

Participant type(s)

Patient

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 enrolment
2. Current hospitalisation of the patient
3. Risk of suicide, item 3 of Hamilton Depression Rating Scale (HAM-D) assessed > 2
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 Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV) at least one year before enrolment
6. Generalized anxiety disorder (GAD) is excluded by module O of the M.I.N.I. and a major

depression is excluded by module A of the M.I.N.I. and by a total score ≤ 16 in the Hamilton Scale of Depression (HAM-D) at screening

6. Non-medical psychiatric treatment (e.g. specific standardized psychotherapy) at least 4 weeks before the study

7. Intake of any prescribed psychotropic medication (see exclusion criterion no. 8) within one year before enrolment.

8. Unacceptability to discontinue or likelihood to need medication during the study that is prohibited as concomitant treatment

9. Clinical significant abnormality of electrocardiogram (ECG) and/or laboratory value(s)

10. Any clinically relevant hepatic, renal [serum creatinine or serum aspartate transaminase (ASAT), alanine transaminase (ALAT) or gamma-GT above three 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, parkinsons disease

11. Any form of diabetes mellitus

12. Clinically significant anaemia

13. Clinically significant thyroid dysfunction as expressed by significant abnormality in thyroid-stimulating hormone (TSH), T3 and/or T4 levels

14. 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)

15. Known hypersensitivity to Rhodiola rosea extract or any ingredient of the drug under study

Date of first enrolment

31/07/2011

Date of final enrolment

30/04/2013

Locations

Countries of recruitment

Austria

Study participating centre

Universitätsklinik für Psychiatrie und Psychotherapie

Wien

Austria

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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