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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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)

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/07/2011

Completion date
30/04/2013

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 handicaped 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

Age group
Adult

Sex
Both

Target number of participants
120

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
1090

Sponsor information

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

Sponsor details
c/o Mrs Susanne Kraft
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