

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

<b>Submission date</b> 12/04/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/06/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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Wien  
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## 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  $\leq 16$  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)

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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes