

Phase III study on the efficacy and safety of Hypericum extract WS® 5570 in patients with a Major Depressive Episode

Submission date 02/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 05/12/2005	Overall study status Completed	☐ Protocol
Last Edited 16/04/2008	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
750801.01.011

Study information

Scientific Title

Study objectives
Difference between active dose and placebo

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/01/2003

Primary study design

Interventional

Study design

Multicentric, randomized, double-blind, placebo-controlled

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major depressive disorder

Interventions

Hypericum extract WS® 5570 600 mg, 1200 mg, placebo

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Hypericum extract WS® 5570

Primary outcome(s)

Change in the 17-HAMD total score

Key secondary outcome(s)

Responder, remitter,
Montgomery-Åsberg Depression Rating Scale (MADRS), Beck Depression Inventory (BDI), Clinical Global Impression (CGI), safety

Completion date

31/08/2004

Eligibility

Key inclusion criteria

1. Diagnosis of a major depressive episode according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (single episode: 296.21, 296.22, recurrent episode: 296.31, 296.32)
2. Severity of depression on the baseline visit: Hamilton rating scale for depression (17-HAMD) total score ≥ 18 and HAMD item 'depressive mood' ≥ 2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Any of the following psychiatric diagnosis according to DSM-IV: schizophrenia (295.x, 297.x, 298.x), acute anxiety disorder (300.x, 302.x) as primary diagnosis, adjustment disorder (309.x), episodes of depression with any characteristics of a psychotic nature (296.24, 296.34), depressive disorders not defined as inclusion criteria (e.g. 300.4, 311), bipolar disorder (296.0, 296.4, 296.5, 296.6, 296.7, 296.8, 301.13), organic mental disorder (International Statistical Classification of Diseases and Related Health Problems - tenth revision [ICD-10]: F06), acute post traumatic stress disorder (309.81), abuse of any substance; risk of suicide
2. Lack of response to any adequate antidepressant therapy in the present episode
3. Duration of the index episode greater than 1 year
4. Concomitant medication with any psychotropic drug
5. Any clinical relevant hepatic, renal, cardiovascular, respiratory, cerebrovascular, metabolic disorder or progressive diseases

Date of first enrolment

01/03/2003

Date of final enrolment

31/08/2004

Locations**Countries of recruitment**

Germany

Study participating centre

Willmar-Schwabe-Straße 4

Karlsruhe

Germany

76227

Sponsor information

Organisation

Schwabe Pharmaceuticals (Germany)

ROR

<https://ror.org/043rrkc78>

Funder(s)**Funder type**

Industry

Funder Name

Dr. Willmar Schwabe GmbH & Co. KG

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?
Results article	results	23/06/2006		Yes	No