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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

Registration date
05/12/2005

Overall study status
Completed

Last Edited
16/04/2008

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

Study design
Multicentric, randomized, double-blind, placebo-controlled

Primary study design
Interventional

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