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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

Contact name
Dr Angelika Dienel

Contact details
Willmar-Schwabe-Straße 4
Karlsruhe
Germany
76227

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Change in the 17-HAMD total score

Secondary outcome measures

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

Overall study start date
01/03/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
320

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)

Sponsor details
Willmar-Schwabe-Straße 4
Karlsruhe
Germany
76227

Sponsor type
Industry

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr. Willmar Schwabe GmbH & Co. KG

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/06/2006		Yes	No