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St Johns wort (SJW) for mild to moderate depression (MDD) in adolescents

Submission date	Recruitment status	[X] Prospectively registered
06/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/07/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/08/2012	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

Protocol serial number
DEMIJO 1.0

Study information

Scientific Title
St Johns wort (SJW) for mild to moderate depression (MDD) in adolescents: a parallel group, randomised, double-blind, placebo-controlled, multicentre trial

Acronym

DEMIJO

Study objectives
Mild to moderate depression (MDD) in adolescents is a severe disorder with high risk of chronic impairment and poor prognosis without sufficient treatment. Recovery in mild to moderate depression will hardly be achieved with only supportive treatment. The following findings in adult St John's wort (SJW) could be an efficacious treatment option for MDD in minors without severe side effects. For SJW no sound data about response/efficacy in adolescents are available. The results of the proposed study will have a tremendous impact on clinical practice given the fact that SJW is one of the most frequently used drugs in minors against MDD in Germany without a sound database neither on efficacy nor on adverse events (AE).

Anticipated start date has been modified from 01/09/2009 to 03/11/2010.

Please note that as of 13/08/2012, this trial is no longer recruiting patients. The anticipated end date has been updated from 01/09/2013 to 01/12/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission der Universität Ulm. Approved 17/03/2010

Study design
Parallel group randomised double-blind placebo-controlled multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate depression (MDD)

Interventions
Experimental intervention: SJW (600 mg/d) and treatment as usual (TAU = psychological support)
Control intervention: placebo and TAU

Acute treatment period: 12 weeks; 13 study visits: 6 office and 7 phone; a follow-up assessment at 24 weeks after the end of the 12-week double-blind acute therapy period is planned.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
St Johns wort (SJW)

Primary outcome(s)
Efficacy of SJW compared with placebo in the acute treatment of adolescents. Measured at baseline and weekly during treatment period.

Key secondary outcome(s))
1. Efficacy
2. Safety
3. Pharmacokinetics
4. Quality of life
5. Social functioning

Measured at baseline and weekly during treatment period.

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Participant is able to understand the study and its procedures according to his or her age. Caregivers have to be able to understand the study, the study procedures, individual consequences for their child.
2. Written consent and assent of the caregivers and participants which is dated by the caregivers /participants before any study exam or procedure is conducted
3. Adolescents (both sexes, aged 12 - 17 [inclusive] years) with mild to moderate MDD at time of signing consent/assent and first visit
4. Symptoms of depression stable for about 6 weeks before entering the trial
5. Female patients must test negative for pregnancy during screening. Furthermore, female patients must agree to abstain from sexual activity or to use a reliable method of birth control as determined by the investigator during the study.
6. Patient's parent/legal representative and patient, if capable, are judged to be reliable by the investigator to keep all appointments for clinical visits, tests, and procedures required by the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
17 years

Sex

All

Key exclusion criteria
1. Other psychiatric disorders (current or within the past year) for:
1.1. Severe depression
1.2. Severe suicidal symptoms for which in-patient treatment is necessary at the time of enrolment
1.3. Bipolar-disorder
1.4. Acute post traumatic stress disorder
1.5. Substance abuse
1.6. Schizophrenia
2. Acute risk of suicide in the opinion of the investigator at Visit 1
3. Other non-psychiatric disorders as specified as follows:
3.1. Diagnosis of epilepsy
3.2. Any intracranial disease
4. Intelligence quotient (IQ) less than or equal to 80
5. Start of psychotherapy (psychotherapy will be allowed if psychotherapy started more than 3 months ago)
6. Treatment with other AD or psychopharmacologically active substances (treatment should be have stopped 5half-lives before entering the trial), except short-term benzodiazepine treatment /corticoid treatment/treatment with methylphenidate (no time restriction but start with stimulant medication must be 3 months before entering the trial)
7. Prior ineffective treatment with SJW or other AD (if treated over a period of more than 1 months)
8. Contraindications or hypersensitivity to SJW (e.g. light allergic skin reactions) or to similar preparation or components of the study medication
9. Pregnancy and breast-feeding
10. Treatment with drugs that interact with SJW or CYP3A4 (e.g., immunosupressants and anti-human immunodeficiency virus [HIV] medication, e.g., ciclosporin, indinavir, other protease-inhibitors; cyotstatics: e.g., imatinib,; anti-coagulant medication: e.g., warfarin/cumarine); medication with pharmacokinetic-antagonistic interactions, e.g., digoxin, theophyllin, hormonal contraceptives, or verapamil, simvastatin, midazolam; medication with pharmacodynamic synergistic interactions, e.g., antidepressants as selective serotonin reuptake inhibitors (SSRI)
11. Patients with intolerance against lactose will be excluded as placebo contains lactose
12. Participation in another clinical trial during the trial or before 3 months of entering the trial

Date of first enrolment
03/11/2010

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Germany

Study participating centre

University Medical Center Ulm
Ulm
Germany
89075

Sponsor information

Organisation
University Medical Center Ulm (Germany)

ROR
https://ror.org/05emabm63

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes