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Effectiveness of Hypericum perforatum and Passiflora incarnata extract combination for treatment of depression and accompanied anxiety

Submission date	Recruitment status	[ ] Prospectively registered
19/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/07/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/07/2006	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives
Ansolin is equal to placebo in treating depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pakistan psychiatric research centre

Study design
Double blind, randomised, multicentre, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Depressive states

Interventions
This is a randomised, double blind, multicentre, parallel group, placebo and active controlled comparison of the efficacy and safety of Ansolin in ambulatory, mildly or moderately depressed patients of eight week duration with a follow-up after four weeks.

After obtaining informed consent patients will complete a pre-study evaluation to assess their suitability to participate. They start with a single-blind placebo period of one week duration and the severity of the depressive symptoms is reassessed thereafter. Eligible patients who do not improve more than 20% on the HAMD-17 will receive one of two treatments: ansolin (containing Hypercicum perforatum and Passiflora incarnata), or a placebo. Patients will be stratified according to their HAMD score (two strata: HAMD total score of 14-17 or 18-24) and centre (three strata). Blindness will be assured by applying the placebo-verum technique.

Treatment with double blind medication will be ended, when the clinical condition worsens during treatment or when improvement stagnates in such a degree that the best interest of the patient is not served by continuation. Both decisions are at the discretion of the investigator. At this moment treatment is initiated with the drugs preferred by doctor and patient. Preferably, after discontinuation of the double-blind medication all assessment will take place as scheduled.

The clinical trial will be ended, when less than 25% of the required number of patients is included within eight months after the initiation of the trial.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hypericum perforatum (St Johns Wort) and Passiflora incarnata (Passion flower)

Primary outcome measure
The efficacy of ansolin in mild to moderate severe depressive states.

Secondary outcome measures
The efficacy of ansolin in the accompained anxiety in depressive states.

Overall study start date
03/07/2004

Completion date
01/05/2006

Eligibility

Key inclusion criteria
1. Male or female patients of eighteen to sixty-five years of age
2. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) diagnosis of mild to moderate (severe) depressive disorder
3. Total severity score of at least 13 and at most 24 at the 17-item Hamilton rating scale for Depression (HAMD) at the entry visit
4. Able to understand the procedures and agreeing to participate by giving written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Patients who respond during the first week with a decrease of the total score of the 17-items HAMD of at least 20%
2.
Women of child-bearing potential without adequate birth-control measures
3. Women who are pregnant or breast-feeding
4. Treatment with Monoamine Oxidase (MAO) inhibitors during the last two weeks prior to the entry visit
5. Treatment with any psychotropic drug during at least the week preceding the entry visit
6. Contraindication or history of hypersensitivity to the study drugs
7. Unstable and/or severe organ system diseases, e.g. neurological, cardiovascular, pulmonary, hepatic, renal, gastrointestinal, endocrine, metabolic, or other
8. History of organ transplantation or Human Immunodeficiency Virus (HIV) positive
9. Usage of immunomodulators, antiretroviral drugs or digoxine
10. Clinical significant abnormalities observed at screening at the discretion of the investigator
11. Substance dependence or abuse according to DSM-IV criteria
12. Bipolar disorder, psychotic features, or any other psychotic disorder
13. Other principal psychiatric diagnosis judged by the investigator to dominate the clinical picture
14. Significant risk for suicide or significant potential for self-harm as judged by the investigator
15. Significant risk for non-compliance with study procedures or drug intake as judged by the investigator

Date of first enrolment
03/07/2004

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
Netherlands

Pakistan

Study participating centre
Tolhuislaan 11 - 13
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Sponsor information

Organisation
Bional Holding BV (The Netherlands)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
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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