

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

<b>Submission date</b> 19/06/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/07/2006	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 Hypericum 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 ansofin in mild to moderate severe depressive states.

**Secondary outcome measures**

The efficacy of ansofin in the accompanied 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

**Website**

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**Funder(s)****Funder type**

Industry

**Funder Name**

Bional Holding BV

**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