

Enhancing cognition in bipolar disorder

Submission date 16/05/2007	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 16/07/2007	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 24/02/2015	Condition category 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

Protocol serial number
2005/165: version 2

Study information

Scientific Title
Enhancing cognition in bipolar disorder

Study objectives
Patients with bipolar affective disorder, currently in remission, will show enhanced cognition on tests of attention, executive function and memory after taking a single dose of modafinil compared with performance on the placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Suffolk Local Research Ethics Committee, 19/08/2005, LREC number: 05/Q0102/71

Study design

Double-blind placebo-controlled cross-over study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bipolar disorder

Interventions

Participants will be randomized to oral administration of one dose of modafinil (200 mg) or one dose of placebo (double blind). After a minimum of one-week washout period a cross-over intervention will be carried out. The interventions started in July 2006.

Updated 24/02/2015: the trial was stopped due to poor recruitment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Modafinil

Primary outcome(s)

Performance on tests of attention, memory and executive function, assessed 2 hours after taking the drug/placebo by the following:

Symptom Rating Scales:

1. Hamilton depression scale
2. Young mania scale
3. Beck depression inventory
4. Apathy scale
5. Epworth sleepiness scale
6. Bond and Lader scale

Neuropsychological Tests: (CAMbridge Neuropsychological Test Automated Battery). [CANTAB])

7. Digit Span
8. Controlled oral word association test
9. Motor Screening

10. Pattern recognition memory test
11. Spatial recognition memory test
12. Big/ little circle
13. Rapid visual information processing task
14. Rey auditory verbal learning test
15. Attentional set shifting task
16. One Touch Tower of London task

All tests will be carried out on both testing sessions (one week apart).

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/08/2008

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. All patients must be able to give informed written consent to participate in the study
2. Aged 18 to 65
3. English should be spoken fluently
4. Participants should be literate and have normal or corrected to normal eyesight
5. All patients must have met Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM IV) criteria for Bipolar I disorder in the past i.e. they must have had an episode of mania or a mixed affective state
6. The Hamilton Depression Rating Scale and Young Mania Scale scores must both be less than eight

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients who currently fulfill criteria for mania, a mixed affective state, hypomania or major depression

2. Patients who score less than or equal to 24 on the Mini-Mental State Examination (MMSE). All patients with a diagnosis of dementia will be excluded after review of case-records and/or discussion with their clinician
3. Current diagnosis of alcohol or drug dependence based on DSM IV criteria
4. History of learning disability (or Wechsler test of Adult Reading score <90) or dyslexia
5. Any known neurological illness (including narcolepsy)
6. Unstable medical illness that may affect cognition (untreated thyroid disease, type I diabetes mellitus or current treatment with steroids)
7. Have received electroconvulsive therapy in the past three months
8. Patients taking herbal remedies such as St Johns Wort or Gingko Biloba
9. Moderate or severe hypertension. All patients should have blood pressure measurements within normal limits (i.e. systolic blood pressure less than or equal to 160 and diastolic blood pressure less than or equal to 90) prior to drug administration
10. Known history of angina or cardiac arrhythmias
11. Pregnant or breastfeeding
12. Patients taking phenytoin (due to possible increase in plasma concentration)
13. Known hypersensitivity to modafinil or its excipients, or to the placebo
14. Participated in another clinical drug trial within the last three months
15. Female patients on an Oral Contraceptive (OC) will need to be counselled about the possibility that modafinil may reduce the effectiveness of the OC. They will only be excluded if they are not willing to take the family planning advice recommendations in the British National Formulary (BNF) (for the short term course of an enzyme inducing drug)
16. Patients who have had any changes to their psychotropic drugs over the past six weeks

Date of first enrolment

01/08/2005

Date of final enrolment

01/08/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

West Suffolk Hospital

Bury St Edmunds

United Kingdom

IP4 5PD

Sponsor information

Organisation

Suffolk Mental Health Partnership NHS Trust (UK)

ROR

<https://ror.org/03400ft78>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Suffolk Mental Health Partnership NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration