# Enhancing cognition in bipolar disorder

Submission date	Recruitment status	Prospectively registered
16/05/2007	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
16/07/2007	Stopped	☐ Results
Last Edited Co	Condition category	Individual participant data
24/02/2015	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

#### Contact name

Dr Judy Rubinsztein

#### Contact details

Wedgwood House West Suffolk Hospital Hardwick Lane Bury St Edmunds United Kingdom IP4 5PD

## 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**

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

#### **Study outputs**

Output type Date created Date added Peer reviewed? Patient-facing? **Details** Participant information sheet 11/11/2025 No Yes

Participant information sheet