ISRCTN93360820 https://doi.org/10.1186/ISRCTN93360820

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	**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

Primary study design
Interventional

Study design
Double-blind placebo-controlled cross-over study

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