

Efficacy of mifepristone in the treatment of bipolar depression

Submission date 22/06/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 21/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 09/09/2009	Condition category Mental and Behavioural Disorders	☐ Individual participant data

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
G0401207

Study information

Scientific Title

Efficacy of Mifepristone (RU-486) in the Treatment of Bipolar Depression, a randomised controlled trial

Acronym

Deathstar

Study objectives

Adjunctive treatment with mifepristone will improve neuropsychological performance and ameliorate depressive symptoms in patients with bipolar depression

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 09/09/09: Newcastle and North Tyneside 1, approved 06/09/2004, ref 04/Q0905/110

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bipolar Depression

Interventions

Adjunctive treatment with mifepristone (600 mg/day for 7 days) versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mifepristone

Primary outcome(s)

1. Spatial Working Memory (CANTAB)
2. Verbal learning

Key secondary outcome(s)

A secondary neuropsychological battery will also be included which examines a broader range of neurocognitive domains, incorporating: short-term memory span, visuo-spatial learning and

memory, executive function, attention, semantic memory and perception of facial expression of emotion. In addition, depressive symptoms measured with the Montgomery and Asberg Depression Rating Scale (MADRS) will also act as secondary outcome measure.

Completion date

30/06/2010

Eligibility

Key inclusion criteria

1. Bipolar Depression (Structured Clinical Interview for Depression [SCID])
2. Age 18-65

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Key exclusion criteria

1. SCID diagnosis of mixed episode
2. Change in medication over the past 4 weeks
3. History of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)
4. Alcohol dependence (within the last 12 months)
5. Current alcohol or substance abuse (within the last month)
6. Previous head-injury associated with loss of consciousness
7. Pregnant
8. Intending to become pregnant
9. Women not using adequate contraception
10. Neurological disorder
11. Endocrine disorder other than corrected hypothyroidism
12. Steroid medication
13. Significant physical health problem
14. Contraindication to study drug

Date of first enrolment

01/05/2005

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Neurology, Neurobiology & Psychiatry

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information

Organisation

The Newcastle, North Tyneside And Northumberland Mental Health NHS Trust (UK)

ROR

<https://ror.org/01ajv0n48>

Funder(s)

Funder type

Research organisation

Funder Name

Stanley Medical Research Institute (UK) and Medical Research Council (MRC) (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/01/2012		Yes	No
Abstract results	abs 448	15/04/2009		No	No