ISRCTN27649427 https://doi.org/10.1186/ISRCTN27649427

Efficacy of mifepristone in the treatment of bipolar depression

Submission date	Recruitment status
22/06/2005	No longer recruiting
Registration date	**Overall study status**
21/09/2005	Completed
Last Edited	**Condition category**
09/09/2009	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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.

Overall study start date
01/05/2005

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100

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
England

United Kingdom

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)

Sponsor details
Dr Roger Paxton
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Sponsor type
Hospital/treatment centre

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

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

Study outputs

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