# Efficacy of mifepristone in the treatment of bipolar depression

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

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

**Prof IN Ferrier** 

#### Contact details

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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

Research and Clinical Effectiveness

Modular Building

St Nicholas Hospital

Gosforth

Newcastle

England

United Kingdom

NE3 3XT

+44 (0)191 2232339

gill.minto@nmht.nhs.uk

#### 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