

# Efficacy of mifepristone in the treatment of bipolar depression

<b>Submission date</b> 22/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/09/2009	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof IN Ferrier

**Contact details**  
School of Neurology, Neurobiology & Psychiatry  
Leazes Wing  
Royal Victoria Infirmary  
Queen Victoria Road  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP  
+44 (0)191 282 4336  
i.n.ferrier@ncl.ac.uk

## 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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	12/01/2012		Yes	No
<a href="#">Abstract results</a>	abs 448	15/04/2009		No	No