

# Resistant Depression - Ketamine Infusion Trial Evaluation

<b>Submission date</b> 21/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/04/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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

**Study website**  
<http://www.red-kite.org.uk>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Rupert McShane

**Contact details**  
Oxford Health NHS foundation trust  
Warneford Lane  
Headington  
Oxford  
United Kingdom  
OX3 7JX  
-  
[rupert.mcshane@oxfordhealth.nhs.uk](mailto:rupert.mcshane@oxfordhealth.nhs.uk)

## Additional identifiers

**EudraCT/CTIS number**  
2009-016941-25

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

8200

# Study information

## Scientific Title

ReD-KITE: Resistant Depression - Ketamine Infusion Trial Evaluation: a phase I, dose escalation, safety study

## Acronym

ReD-KITE

## Study objectives

Several recent studies have shown that low dose intravenous ketamine infusion has a dramatic antidepressant effect in patients with treatment resistant depression.

ReDKITE aims to explore this new treatment further, by evaluating the safety and tolerability of repeated ketamine infusions in adult patients of any age with treatment resistant depression. By 'treatment resistant' we mean individuals that have received at least 2 adequate trials of antidepressants and these have been unsuccessful.

We are interested in:

1. How well a low dose of ketamine is tolerated in people with treatment resistant depression (are there any side effects)
2. Whether ketamine improves mood for people with treatment resistant depression, and if so, how long this can last

Please note that as of 25/10/2012, the anticipated end date of this trial was updated from 01/09/2012 to 31/05/2013.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Oxfordshire REC B approved on the 13th November 2009 (ref: 09/H0605/118)

## Study design

Single centre non-randomised interventional phase I treatment trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Can be found at <http://www.red-kite.org.uk/id6.html>

## Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Depression; Disease: Depression

## Interventions

All participants receive the same study drug. In stage 1 participants receive the drug once a week for three weeks and in stage 2 they receive the study drug twice a week for 3 weeks. The study drug is Ketalar® (ketamine) at a dose of 0.5 mg/kg. This is given intravenously over a 40 minute period. Total study duration including follow-up is 3 months 3 weeks.

Study entry: registration only

## Intervention Type

Drug

## Phase

Phase I

## Drug/device/biological/vaccine name(s)

Ketamine

## Primary outcome measure

Exploring the safety and tolerability of repeated doses of ketamine.

### Stage 1:

Measured at baseline, day 0 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes) day 6, day 7 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 13, day 14 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes) day 21, day 28, day 42, day 70 and day 98.

### Stage 2:

Measured at baseline, day 0 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 3 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 6, day 7 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 10 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 13, day 14 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 17, day 21, day 28, day 42, day 70 and day 98.

## Secondary outcome measures

Monitoring mood.

### Stage 1:

Measured at baseline, day 0 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes) day 6, day 7 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 13, day 14 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes) day 21, day 28, day 42, day 70 and day 98.

### Stage 2:

Measured at baseline, day 0 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 3 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 6, day 7 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 10 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 13, day 14 (-20, 20, 40, 60, 80, 100, 120 and 360 minutes), day 17, day 21, day 28, day 42, day 70 and day 98.

**Overall study start date**

22/02/2010

**Completion date**

31/05/2012

## **Eligibility**

**Key inclusion criteria**

Current inclusion criteria as of 25/10/2012:

1. Suffering from Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) major depression (uni-polar or bi-polar)
2. Current or past history of lack of response to two adequate antidepressant trials operationally defined using the Antidepressant Treatment History Form (ATHF)
3. Medically fit to receive ketamine in opinion of Consultant Anaesthetist
4. Aged over 18 years, either sex
5. Willing and competent to give informed consent for participation in the study
6. Good understanding of English
7. If a daypatient, must be accompanied until 6 am on the day after each treatment by a competent adult
8. Participant has previously been assessed by a psychiatrist.
9. Able (in the Investigators opinion) and willing to comply with all study requirements.
10. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study and any clinically significant changes.

Previous inclusion criteria until 25/10/2012:

1. Suffering from Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) major depression
2. Score of 18 or higher on Hamilton Depression Rating Scale (HDRS) at screening and baseline
3. Current or past history of lack of response to two adequate antidepressant trials operationally defined using the Antidepressant Treatment History Form (ATHF)
4. Depression to a level that they are being considered for alternative more intense treatment such as electroconvulsive therapy (ECT)
5. Medically fit to receive ketamine in opinion of Consultant Anaesthetist
6. Aged over 18 years, either sex
7. Competent to consent to research
8. Good understanding of English
9. If a daypatient, must be accompanied until 6 am on the day after each treatment by a competent adult

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 24; UK sample size: 24

**Key exclusion criteria**

Current exclusion criteria as of 25/10/2012:

1. Schizophrenia or schizoaffective disorder
2. Dementia or diagnosis of mild cognitive impairment
3. Closed angle glaucoma
4. Individuals with a poor understanding of English
5. Female participants who are pregnant, lactating or planning pregnancy during the course of the study.
6. Participant who is terminally ill
7. Known hypersensitivity to the drug Ketamine
8. Uncontrolled hypertension
9. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participants ability to participate in the study.

Previous exclusion criteria until 25/10/2012:

1. Serious suicide risk as judged by the treating consultant
2. Schizophrenia or schizoaffective disorder
3. History of illegal substance misuse
4. Alcohol dependence in last 2 years
5. Dementia or diagnosis of mild cognitive impairment
6. Antidepressant-induced mania
7. Manic episode in last 2 years
8. Closed angle glaucoma
9. Neuropathic pain
10. On Section of Mental Health Act
11. If daypatient and cannot be accompanied by a competent caregiver
12. Individuals with a poor understanding of english
13. Participant does not have/loses capacity

**Date of first enrolment**

22/02/2010

**Date of final enrolment**

31/05/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Oxford Health NHS foundation trust**  
Oxford  
United Kingdom  
OX3 7JX

## **Sponsor information**

### **Organisation**

Oxford Health NHS foundation trust (UK)

### **Sponsor details**

Research and Development Department  
Warneford Lane  
Headington  
Oxford  
England  
United Kingdom  
OX3 7JX

### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.obmh.nhs.uk>

### **ROR**

<https://ror.org/04c8bjx39>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Institute for Health Research

### **Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results:	01/06/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No