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Resistant Depression - Ketamine Infusion Trial Evaluation

Submission date	Recruitment status	[ ] Prospectively registered
21/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/04/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-016941-25

Protocol serial number
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 anti-depressants 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Oxford Health NHS foundation trust
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
Oxford Health NHS foundation trust (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

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:	01/06/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes