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# Ketamine in treatment-resistant major depression

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 05/06/2006 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 03/07/2006 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 04/02/2015 | Mental and Behavioural Disorders | [ ] Record updated in last year |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
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**Contact details**
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## Additional identifiers

**EudraCT/CTIS number**
2006-001798-95

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
170965

## Study information

## Scientific Title
Ketamine in treatment-resistant major depression

## Study objectives
The purpose of this trial is to study if ketamine-infusion relieves symptoms of depression among patients, who have not obtained sufficient response from conventional treatment. The study is a randomised, placebo-controlled, parallel-group trial.

Updated 04/02/2015: the trial was stopped on 14/08/2007 due to major difficulties in recruiting eligible subjects.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The Ethical Committee of the Northern Savo Hospital District (formerly "The ethical committee of University of Kuopio and Kuopio University Hospital"), approval was dated 14/03/2006 (ref: 30 /2006). The study was also approved by the National Agency for Medicines on 12/05/2006 (ref: 81/2006).

The Ethical Committee of the Northern Savo Hospital District has approved the amendment of the exclusion criteria on 12/12/2006

## Study design
Randomised placebo-controlled parallel-group multi-centre trial

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Treatment-resistant major depression

## Interventions
Ketamine-infusion (0.5 mg/kg) or placebo-infusion (0.9 % NaCl) during 40 minutes.

## Intervention Type
Drug

## Phase
Not Applicable

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

### Primary outcome measure
Change in HAMD-17 scores during the first seven days after infusion compared with scores on control day (before infusion).

### Secondary outcome measures
1. 15-D instrument to indicate quality of life
2. HAMD/ Melancholia Scale (MES)
3. Symptom Checklist 90-scale (SCL-90)

### Overall study start date
09/06/2006

### Completion date
30/09/2007

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
1. Major depression disorder (Diagnostic and Statistical Manual of mental disorders [DSM-IV] 296.2 or 296.3) or type two bipolar affective disorder, last phase with depressive symptoms
2. Depressive symptoms at least at moderate level (Hamilton Depression rating scale [HAMD-17] score 16 or more)
3. Age 18 to 55 years
4. Insufficient response to at least two different antidepressants
5. No substantial changes in current antidepressant treatment during the last four weeks and changes in pharmacotherapy have not been planned for the following two weeks

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
100 patients

### Key exclusion criteria

1. Serious somatic disease (cardiac insufficiency, untreated hypertension, increased cerebral pressure, diseases in the central nervous system, increased intraocular pressure (glaucoma), hepatic disease, porphyria, thyroid disease, infection in lungs or in upper respiratory track, epilepsy)
2. Theophyllin medication, or use of anticonvulsants or drugs affecting glutamatergic system
3. Proneness to psychotic symptoms (psychosis diagnosed in first degree relatives)
4. Increased suicide risk
5. Pregnancy
6. Substance abuse during the last three weeks
7. Exceptionally large dosage of antidepressants (dosage per day more than recommended in Pharmaca Fennica) (this was amended 19/12/2006)
8. Exceptionally large dosage of benzodiazepines (diazepam equivalent dose more than 30 mg /day)

### Date of first enrolment
09/06/2006

### Date of final enrolment
30/09/2007

## Locations

### Countries of recruitment
Finland

### Study participating centre
**Niuvanniemi Hospital**
Kuopio
Finland
FI-70240

## Sponsor information

### Organisation
University of Kuopio (Finland)

### Sponsor details
PO Box 1627
Kuopio
Finland
FI-70211

### Sponsor type
University/education

### Website

http://www.uku.fi/english/

**ROR**
https://ror.org/00cyydd11

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Niuvanniemi Hospital (Finland)

# 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