# Ketamine in treatment-resistant major depression

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

Clinical Trials Information System (CTIS)

2006-001798-95

Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

# 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)

#### **ROR**

https://ror.org/00cyydd11

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Niuvanniemi Hospital (Finland)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration