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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

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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