A pilot study on oral esketamine for depression and demoralization in patients with advanced cancer receiving palliative care

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Evaluation of the feasibility of a trial on the efficacy of oral esketamine for the treatment of depression and/or demoralization in patients with advanced cancer who receive palliative care.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON49647

Source
ToetsingOnline

Brief title
Esketamine for depression and demoralization

Condition

- Mood disorders and disturbances NEC

Synonym
hopelessness, Sadness

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Advanced cancer, Demoralization, Depression, Esketamine

Outcome measures

Primary outcome

The primary outcome of this pilot study is to decide whether it is feasible to conduct a larger trial on the effectiveness of oral esketamine for the treatment of depression and demoralization in patients with advanced cancer receiving palliative care. This will be judged by preliminary effectiveness, safety, tolerance and acceptability of the intervention, and acceptability of the study procedures. These parameters will be assessed both quantitatively and qualitatively.

Secondary outcome

• Decrease in self-reported depression severity, as expressed by a decrease in total score on the Beck Depression Inventory (BDI);

• Changes in patients* quality of life, as expressed by a decrease in total score on the McGill Quality of Life Questionnaire (MQOL);

• Decrease in anxiety, expressed as a decrease in total score on the Death and Dying Distress Scale (DADDS);

• Experiences of participants during the trial, as assessed by in-depth, semi-structured interviews.

Study description

Background summary

Patients with cancer for whom no curative treatment options remain often experience depression and/or demoralization. Currently available treatments are inadequately able to diminish these conditions within a timely matter. Ketamine, an N-methyl-D-aspartic acid (NMDA) glutamate receptor antagonist, has shown efficacy as a rapid acting antidepressant and is hypothesized to constitute an acceptable and effective treatment option for depression and demoralization in advanced cancer patients.

Study objective

Evaluation of the feasibility of a trial on the efficacy of oral esketamine for the treatment of depression and/or demoralization in patients with advanced cancer who receive palliative care.

Study design

A single center, open-label, phase II, clinical pilot study aimed to assess the feasibility of a future trial, based on limited efficacy testing, safety, tolerability, acceptability, feedback of participants, and recruitment/retention rates of oral esketamine for the treatment of depression and demoralization in advanced cancer patients.

Intervention

Patients will receive an oral dose of 0.5 mg (minimum) to 3.0 mg (maximum) S-ketamine twice per week for a five week period.

Study burden and risks

Participation in this pilot study is expected to pose some burden to participants (given the frequency of the treatment sessions) and may directly benefit participants. The treatment sessions will take place at the department of Oncology and will last for approximately 150 minutes. Study visits are kept to a minimum in both amount and duration, so as to minimize participant burden. Follow-up meetings may be conducted by phone.

At sub-anaesthetic dosages, acute side effects of ketamine treatment are common, but most of them resolve shortly after dose administration. Limited data from other populations are available regarding cumulative and long-term risks of ketamine use.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Older than 18 years of age;
• Sufficient understanding of spoken and written Dutch;
• DSM-5 diagnosis of MDD, first or recurrent episode, ascertained by the Mini International Neuropsychiatry Interview (MINI-plus) and/or demoralization as indicated by a score of 30 on the Demoralization Scale;
• Advanced malignancy with no curative antitumor treatment possibilities as determined by a physician at the oncology department.

Exclusion criteria

- Depression with psychotic features, according to the DSM-5;
- Previous or comorbid schizophrenia spectrum or other psychotic disorder according to the DSM-5, not including previous MDD with psychotic features;
- Comorbid moderate or severe dependence of alcohol or drugs according to the DSM-5, not including tobacco-related and caffeine-related disorders;
- Comorbid delirium, according to the DSM-5;
- Recent (within the last 4 weeks) or current use of non-prescribed psychoactive compounds, including cannabis and Saint John*s wort;
- Electroconvulsive therapy (ECT) sessions or antidepressant treatment changes planned for the period of the study;
- Current use of benzodiazepines and benzodiazepine-like agents (zolpidem, zopiclone) in excess of 2 mg lorazepam or an equivalent per day;
- Current use of ketamine;
- Mental incompetence to provide informed consent;
- Presence of any contra-indication for ketamine use. Ketamine is contra-indicated in persons with uncontrolled blood pressure, persons whom have shown hypersensitivity to the drug or its components, in persons with eclampsia or pre-eclampsia, severe coronary or myocardial disease, or a cerebrovasculair accident or cerebral trauma, and in patients who use medication that ketamine interacts with on a major level, such as monoamine oxidase inhibitors (MAOi).
- Inability to comply with treatments and/or assessments.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-01-2021
Enrollment:	10

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	S-ketamine
Generic name:	S-ketamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-09-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-02-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-04-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-09-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-001621-27-NL
CCMO	NL69770.042.19