# A pilot study on oral S-ketamine for depression and demoralisation in patients with advanced cancer receiving palliative care

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Treatment with oral S-ketamine, twice a week for five weeks, can improve symptoms of depression and/or demoralization in patients with advanced cancer for whom no curative treatment options remain.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29195

**Bron**
Nationaal Trial Register

**Verkorte titel**
TBA

**Aandoening**

Depression and demoralisation, advanced (non-curable) cancer

### Ondersteuning

**Primaire sponsor:** Investigator-initiated
**Overige ondersteuning:** Investigator Initiated

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

1. Limited efficacy testing:
1.1) Decrease in depression symptom severity, expressed as a decrease in total score on the Hamilton Depression Rating Scale (HDRS17);
1.2) Decrease in demoralization severity, expressed as a decrease in total score on the DS;
2. Safety/tolerability:
2.1) Systematic Assessment for Treatment Emergent Effects (SAFTEE);
2.2) The Iowa Sleep Disturbance Inventory (ISDI);
2.3) The Dissociation Tension Scale (DSS);
2.4) Interstitial Cystitis Symptoms and Problems Index (ICSI/ICPI):
2.5) Monitoring of body weight, blood pressure and liver enzyme levels;
3. Recruitment/retention rates.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: 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.
Objective: evaluating the feasibility of a future randomized controlled trial (RCT) for the efficacy of oral ketamine in the treatment of depression and/or demoralization in patients with advanced cancer for whom no curative anti-cancer treatments remain.
Study design: a single center, open-label, phase II, clinical pilot study aimed to assess the feasibility of a future randomized controlled trial, based on limited efficacy testing, safety, tolerability, acceptability, participation experience, and recruitment/retention rates of oral S-ketamine for the treatment of depression and demoralization in advanced cancer patients.
Study population: 10 advanced cancer patients for whom no curative treatment options remain, age 18 or older, recruited within a 12-month period from the department of medical oncology from the University Medical Center of Groningen (UMCG).
Intervention: patients will receive an oral dose of 0.5 mg (minimum) to 2.5 mg (maximum) S-ketamine twice per week for a five week period.
Main study parameters/endpoints: Hint of efficacy of the intervention defined as a clinically important reduction in depression and/or demoralization in at least 30% of participants who commenced treatment. Feasibility of the intervention will be judged based on safety, tolerability and acceptability as indicated by (1) greater than 80% of significant adverse effects resolving within 120 minutes of each administration, (2) less than 20% dropout rate secondary to adverse effects and (3) feedback from participants regarding treatment

sessions and assessments.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: participation in this pilot study is expected to pose minimal burden to participants 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. Where possible, treatment and study visits are combined. Follow-up 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.

### Doel van het onderzoek

Treatment with oral S-ketamine, twice a week for five weeks, can improve symptoms of depression and/or demoralization in patients with advanced cancer for whom no curative treatment options remain.

### Onderzoeksopzet

Baseline
Folluw-up 1 (5 weeks after start intervention)
Follow-up 2 (8 weeks after start intervention)
Follow-up 3 (10 weeks after start intervention)

### Onderzoeksproduct en/of interventie

Oral S-ketamine, twice weekly for five weeks

## Contactpersonen

### Publiek

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### Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Male or female;
• Older than 18 years of age;
• Signed informed consent;
• Good 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 DS;
• Advanced malignancy with no curative antitumor treatment possibilities as determined by a physician at the oncology department.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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;
• In patients with seizures;
• Presence of any contra-indication for ketamine use. Ketamine is contra-indicated in persons with uncontrolled blood pressure would constitute a serious hazard, 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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 10-06-2019 |
| Aantal proefpersonen: | 10 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7706 |
| Ander register | METC UMCG : METC201900242 |

# Resultaten