Ketamine Trial for Acute suicidality - pilot

Gepubliceerd: 02-09-2020 Laatst bijgewerkt: 13-01-2025

A dose of 75mg of intranasal ketamine lowers suicidal ideation

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

Samenvatting

ID

NL-OMON20015

Bron
NTR

Verkorte titel
KETA-pilot

Aandoening

Acute Suicidality

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: ZonMw, Suicide Prevention Call

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in suicidality scores on the Beck Scale for Suicidal Ideation (BSSI) between baseline and 180 minutes after 75 mg intranasal ketamine administration.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Suicide is currently one of the three leading causes of death in the Netherlands in people aged 15-44 and has a substantial impact on families and society (1). Nevertheless, to date no evidence based pharmacological intervention for acute suicidality exists. Subanesthetic doses of intravenous ketamine have been shown to immediately resolve depressive symptoms and suicidal ideation in depressed patients (2, 3). However, this effect was never investigated for suicidality per se. Herewith, we propose a multicenter double blind randomized placebo controlled trial in 100 subjects presenting with acute suicidality regardless of the underlying diagnosis, to test the hypothesis that a single dose of 75mg intranasal ketamine is able to diminish acute suicidal ideation and behaviour. Additionally, we will examine ketamine's anti-suicidal mechanism of action by measuring plasma, serum and neuroimaging markers. This study may result into a readily available and easily applicable intervention for the treatment of acute suicidality.

Objective:
The objective of the main KETA-study is to test the hypothesis that a dose of 75mg of intranasal ketamine lowers suicidal ideation and behaviour significantly more than active placebo: midazolam. First, a feasibility pilot with 12 subjects, who will all receive ketamine, will be performed.

Study design and population:
This is a feasibility pilot study for the larger KETA-trial: a total of 12 subjects will be included. They will receive an intranasal dose of 75mg . At baseline and at 60 and 180 minutes, 1, 3 and 7 days after ketamine administration, the Beck Scale for Suicide Ideation will be administered. Blood will be taken at 0 and 180 minutes to assess fatty-acid profiles, Brain Derived Neurotrophic Factor (BDNF) and ketamine concentrations. One day after administration, in persons who provided informed consent for participation in the imaging study, magnetic resonance scans will be performed (diffusion tensor imaging (DTI), resting state functional magnetic resonance imaging (fMRI) and magnetic resonance spectroscopy (MRS)). Prior to the RCT, we will perform a small-scale feasibility study in the UMCG (n=12), which is described in paragraph 8.3.1.

Main study parameters/endpoints:
Primary: Change in suicidality scores on the Beck Scale for Suicidal Ideation (BSSI) between baseline and 180 minutes after 75 mg intranasal ketamine.
Secondary: Change in Montgomery Asberg Depression Rating Scale (MADRS), the Clinical Global Impression (CGI), the Systematic Assessment for Treatment Emergent Events (SAFTEE) and the Clinician Administered Dissociative States Scale (CADSS) (4), change in serum and plasma BDNF concentrations from 0 to 180 minutes, fatty acid concentrations at baseline, plasma ketamine concentrations at 180 minutes after intervention, functional and structural frontolimbic connectivity patterns, hippocampal volume and glutamate levels.

Nature and extent of the burden and risks associated with participation is considered moderate: The expected side effects of 75mg intranasal ketamine are minor. The most commonly described side-effect is a feeling of dissociation. To date, no serious adverse event related to the intervention has occurred in low-dose ketamine trials for mood disorders. However, all participants that are to be included, have a high risk of attempting or committing suicide, therefore, the chance that a SAE might occur, is relatively high, and we will therefore classify the risk level of this study as moderate.
The expected benefit may be significant in terms of immediate reduction of suicidal ideation and behaviour.

Doel van het onderzoek

A dose of 75mg of intranasal ketamine lowers suicidal ideation

Onderzoeksopzet

T0, T 1 hour, T3 hours, T1 day, T3 days, T7 days.

Onderzoeksproduct en/of interventie

intranasal ketamine

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Acute suicidality: suicidal thoughts and/or behaviour have increased within the last 24 hours.
BSSI score ≥ 7
Subjects are in the age of 18-70

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Earlier participation in this study
Psychosis (as a primary diagnosis) (depression with psychotic features will not be an exclusion criterion per se).
Schizophrenia or another primary psychotic disorder
History of PCP- or ketamine addiction
Being under influence of GHB (Substance abuse in the (recent) history is not an exclusion criterion per se (with the exception of current GHB-intoxication and a high blood alcohol concentration, and intoxications leading to medical unstable conditions). Use of GHB will be assessed by asking the participant, since urinary analysis is relatively unreliable, and waiting for results of the blood test will, given the acute nature of this study, be too time consuming.
A blood alcohol concentration (BAC) of > 0.05%
Clinically significant and unstable infectious, immunological, neurological cardiovascular, gastro-intestinal, pulmonary, renal, ophthalmological (glaucoma), hepatic, endocrine or haematological disorder, a myocardial infarction, micturition problems or a complex surgical problem that needs immediate attention.
Presence of any contra-indication for ketamine use, such as severe high blood pressure, a recent myocardial infarction or relevant cardiac problems, severe thyroid problems, severe liver problems, severe kidney problems, epilepsy and increased intracranial pressure.
A known hypersensitivity for ketamine
Concomitant use of a MAO-inhibitor
Severe nose congestion or nasal polyps
Pregnancy or giving breastfeeding
Women in the reproductive age using unreliable contraception
Being unable to answer the questionnaires
Legal incompetency with regard to participation in this study
No informed consent

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:	02-09-2020
Aantal proefpersonen:	12
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

ID: 52646
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8873
CCMO	NL74304.042.20
NTR-new	NL3213
NTR-old	NTR3364
Ander register	EudraCT : 2011-001820-39
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON52646

Resultaten