Ketamine Trial Amsterdam (KETA), pilot

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A single subanesthetic dose of intranasal ketamine is able to diminisch acute suicidal ideation and behaviour, regardless of the underlying diagnosis.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26105

Bron
Nationaal Trial Register

Verkorte titel
KETA pilot

Aandoening

(acute) suicidality, depression, personality disorders, substance use disorder.
(acute) suïcidaliteit, depressie, persoonlijkheidsstoornissen, middelenmisbruik

Ondersteuning

Primaire sponsor: University Medical Center Amsterdam, location AMC
Overige ondersteuning: ZonMw, suicide prevention grant

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 compared to 3.8 mg intranasal midazolam (placebo).

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. 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. However, this effect was never investigated for suicidality per se. Herewith, we propose a multicenter double blind randomized placebo controlled trial in 12 subjects as a pilot for the main study with 144 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:

To test the hypothesis that a dose of 75mg of intranasal ketamine lowers suicidal ideation and behaviour significantly more than active placebo: midazolam.

Study design and population:

This is a multicenter double blind randomized placebo controlled study: a total of 144 subjects will be included. They will receive an intranasal dose of 75mg ketamine or 3.8mg midazolam. At baseline and at 60 and 180 minutes, 1, 3 and 7 days and 6 and 12 months 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)).

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 administration compared to 3.8 mg intranasal midazolam (placebo).
Secondary: Change in Montgomery Asberg Depression Rating Scale (MADRS), Brief Psychiatric Rating Scale – Positive Symptoms Subscale (BPRS-PS) (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 negligible: 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. The expected benefit may be a significant in terms of immediate reduction of suicidal ideation and behaviour.

Doel van het onderzoek

A single subanesthetic dose of intranasal ketamine is able to diminisch acute suicidal ideation and behaviour, regardless of the underlying diagnosis.

Onderzoeksopzet

T0 (baseline)

1 hour after intervention

3 hours

1 day

3 days

7 days

6 months

12 months

Onderzoeksproduct en/of interventie

-ketamine nasal spray 75 mg

-midazolam nasal spray 3,8 mg (active placebo)

Contactpersonen

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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.

-score on the Beck Scale for Suicide Ideation (BSSI) > or = 7

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Earlier participation in this study

-Psychosis

-Schizophrenia or another psychotic disorder

-History of PCP- or ketamine addiction

-Being under the influence of GHB (Substance abuse in the (recent) history is not an exclusion crtierion per se (with the exception of GHB and high blood alcohol concentration, and intoxications leading to medical unstable conditions)
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

-A known hypersensitivity for ketamine

-Concomitant use of a MAO-inhibitor

-Severe nose congestion or nasal polyps

-Pregnancy or giving breastfeeding

-Women using unreliable contraception

-Being unable to answer the questionnaires

-Legal incompetency

-No informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-08-2018
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-08-2018
Soort:	Eerste indiening

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	NL7215
NTR-old	NTR7414
Ander register	537001004 (ZonMw project number) : ABR 55438

Resultaten