A randomised, double blind, placebo-controlled cross-over study to investigate the effects of intravenous S(+)-ketamine on brain activation in three groups of women: healthy participants, healthy participants prone to depression and patients with fibromyalgia.

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Objective 1: To determine the effects of S-ketamine on brain activation in healthy women, healthy women prone to depression and fibromyalgia patients.Objective 2: To determine the effects of S-ketamine on mood and other depression-related behavioral...

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

Summary

ID

NL-OMON49216

Source
ToetsingOnline

Brief title
SoKET

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, unhappiness

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Depression, Ketamine, MRI

Outcome measures

Primary outcome

Brain activation: degree of increase or decrease by ketamine.

Secondary outcome

Psychological measures to assess depression.

Study description

Background summary

The NMDA receptor antagonist ketamine is used as an anesthetic, painkiller and, more recently, also as an antidepressant, even though the neural mechanism of its antidepressant action is still unknown. Ketamine causes rapid improvements in mood and suicidality in treatment-resistant patients (Berman et al., 2000; Caddy, Giaroli, White, Shergill, & Tracy, 2014; Krystal, Sanacora, & Duman, 2013; Murrough et al., 2013; Singh et al., 2016; Zarate et al., 2006). However, the effects of ketamine in groups of depressed patients other than treatment-resistant / severely depressed, are still unknown. Previously, we investigated the effects of S(+)-ketamine on brain activation in healthy male participants (protocol nr P10.136) but the results are difficult to extrapolate to depressed patients as well as to women. To further elucidate the (neural) mechanisms of ketamine, which may underlie its (rapid) antidepressant response, we will investigate the effects of ketamine on brain activation in healthy women, women prone to depression and fibromyalgia patients.

Study objective

Objective 1: To determine the effects of S-ketamine on brain activation in healthy women, healthy women prone to depression and fibromyalgia patients.
Objective 2: To determine the effects of S-ketamine on mood and other depression-related behavioral meaures.

Study design

Placebo-controlled crossover.

Intervention

Intravenous administration of S(+)-ketamine (0.4 mg/kg) and placebo.

Study burden and risks

Mild to moderate: psychomimetic side effects during exposure to ketamine.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Right-handed female participants 18-45 years old, naive to ketamine and pre-screened using the M.I.N.I (Mini International Neuropsychiatric Interview version 5.0.0) and BDI-II (Beck Depression Inventory second edition). Group 1: healthy, no history of depression as indicated by the M.I.N.I. and BDI score < 5. Group 2: prone to depression: currently only sub-clinical symptoms indicated by a BDI score ranging from 5 to 17, but previous episode (1 or 2) of clinical depression as indicated by the M.I.N.I. Group 3: pain patients diagnosed with fibromyalgia (meet the 2010 American College of Rheumatology diagnostic criteria), who also show sub-clinical symptoms of depression as indicated by the M.I.N.I. and a BDI score ranging from 5 to 17.

Exclusion criteria

Currently clinically depressed and/or on antidepressant medication; obesity (BMI > 30); significant history of any cardiac or vascular disorder, asthma or other pulmonary disease, major gastrointestinal abnormalities, peptic ulceration, hepatic, neurological, psychiatric, haematological (including bleeding disorders), endocrine, renal, or major genitourinary disease.
History of chronic alcohol or illicit drug use; the contraindications for MRI as defined by the MR safety committee of the department of Radiology, LUMC; claustrophobia; the presence of pain syndromes other than fibromyalgia.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2017
Enrollment:	63
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketamine
Generic name:	Esketamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	10-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	30-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	28-01-2021

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2016-003913-91-NL
CCMO	NL59356.058.16