A double-blind, randomized, three-way cross-over trial to develop a pharmacologic challenge with ketamine.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON34124

Source
ToetsingOnline

Brief title
ketamine-challenge

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorder, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: ketamine, pharmacological challenge, psychomimetic symptoms

Outcome measures

Primary outcome

Positive and negative syndrome scale (PANSS), pre-pulse inhibition (PPI),

visual analogue scales (VAS Bowdle and VAS Bond and Lader), eye movements

(saccadic and smooth pursuit), pupillometry, body sway and pharmacokinetics

(S(+)-ketamine and S(+)-norketamine).

Secondary outcome

N/A

Study description

Background summary

S(+)-ketamine is a fast acting anesthetic, that induces a dissociative anesthesia through NMDA antagonism. In a subanesthetic dose, ketamine has been shown to induce psychomimetic symptoms in both healthy volunteers and patients with schizophrenia. Therefore, ketamine could be used as an in-human model for psychosis in healthy volunteers.

Study objective

The objectives are to assess the pharmacokinetic and pharmacodynamic effects of sub-anesthetic ketamine administration, to assess the optimal dose of ketamine and gender differences, to compare different oucome measures for psychomimetic symptoms and to assess the role of personality, psychotic proneness and genetics on the level of effect.

Study design

This will be a double-blind, randomized, three-way cross-over trial.

Intervention

S(+)-ketamine or placebo, given as an intravenous infusion using target control drug delivery.

Study burden and risks

N/A

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

Age between 18 and 45 (extremes included)
Body Mass Index (BMI) between 18 and 30 kg/m2 (extremes included)
Mild cannabis users (defined as >= 4 times in last year and <= 1x/week in last year)

Willing to provide informed consent to participate in the study and to comply with all study procedures

Exclusion criteria

Clinically significant (history of) disease as determined by medical history, physical examination, ECG or routine blood chemistry, hematology or virology tests.
Clinically significant (history of) psychiatric illnesses (including substance abuse) or (history of) psychotic symptoms
Family history of relevant psychiatric disorders (first degree) and/or psychotic disorders (first and second degree)
Smokes more than five cigarettes a day
Positive urine drug screen for recreational drugs (i.e. cocaine, opioids, benzodiazepines, amphetamines, metamphetamines, MDMA or THC)
Positive urine pregnancy test or breastfeeding
Exposure to medication (including St. John's Wort) known to interfere with CYP3A4 metabolism within 14 days prior to dosing
Unable or unwilling to refrain from smoking, heavy physical exercise or the use of alcohol, xanthine, or grapefruit juice 24 hours prior to dosing until discharge.
Blood loss or donation outside the limits of the Dutch blood bank (Sanquin)
Participation in a clinical study within the past three months, or participation within four or more clinical studies in the past twelve months

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2011

Enrollment:	24
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2010-022203-21-NL
CCMO	NL33486.058.10