A randomised, double blind, placebo-controlled cross-over study to investigate the effects of intravenous S(+)-ketamine on functional brain connectivity using fMRI in healthy volunteers.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34353

Source
ToetsingOnline

Brief title
The F-KET Study

Condition

- Other condition

Synonym
not applicable

Health condition

fMRI onderzoek in gezonde vrijwilligers

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: fMRI, resting state network, S(+)-ketamine

Outcome measures

Primary outcome

resting state network (fMRI)

Secondary outcome

arterial spin labeling (fMRI)

plasma concentrations of S(+)-ketamine and S(+)-norketamine

pain relief

side effects

Study description

Background summary

Many drugs influence the central nervous system, therefore is it important to have extensive knowlegde of the pharmacological activity and the side effects. We know that S(+)-ketamine influences the central nervou system, but we don't know exactly were and how it works.

Study objective

By means of resting state network measurments using fMRI we hope to gain more knowlegde about the actions (for example as an analgesic) an side effects of S(+)-ketamine on the central nervous system at different doses. Also blood

samples will be collected to measure ketamine in the plasma, which can be linked to the effects and side effects of ketamine.

Study design

A randomised, double blind, placebo-controlled cross-over study. There are 2 study days. On the first study day the volunteers receives intraveous S(+)-ketamine or NaCl 0,9% during 2 hours continuously in two doses, each 1 hour. On the second study day the volunteer receives the other medication. On preset times before, during and after the infusion fMRI scans will be made to look at resting state network, also blood samples will be collected from the second iv, heat pain tests will be performed and volunteers are asked to complete questionnaires about side effects.

Intervention

Intravenous infusion of S(+)-ketamine at 20 mg/70 kg/hr for 1 hour, thereafter 40 mg/70 kg/hr for 1 hour, or an infusion with NaCl 0,9%.

Study burden and risks

The study consists of one medical examination, 1 pratice session and 2 study days, totaling about 14 hours, for which the volunteer will be paid. Two intravenous lines will be inserted, one of which will be used to collect blood samples, about 100 ml per study day, hereby preventing frequent venapunctures. Side effects of S(+)-ketamine like nausea, dizziness, dreams, diplopia, blurry vision and a rise in blood pressure can occur. These side effects are mild and quickly spontaneously disappear on termination of the medication. Bruising can occur on the locations were the iv lines were inserted, they will disppear spontaneously. Damage to the body caused by MRI can occur on the instance that metal is present in the body (this damage will be prevented by specifically asking the volunteers about this and by naming all examples).

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

healthy volunteers
age 18-45
right handed
naive to Ketanest-S

Exclusion criteria

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 illness, condition or medication use that, in the opinion of the investigator, might interfere with optimal participation, confound the results of the study or pose additional risk in administering S(+)-ketamine to the subject or in making the MRIs
History of chronic alcohol or illicit drug use;
Unable to refrain from quinine containing products and grapefruit or grapefruit juice from 7 days prior to study start until the last study day.
Metal medical devices like pacemakers, knee or hip prosthesis, ear implants, vessel clips, subcutaneous insulin pumps or carries metal particles (e.g. metal splinter in the eye) inside the body.
Claustrophobia.
Allergy to study medications;

Not able to maintain a regular diurnal rhythm.

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):	29-03-2011
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketanest-S
Generic name:	S(+)-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	EUCTR2010-021517-23-NL
CCMO	NL33048.058.10