The F-KET study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23425

Source
NTR

Health condition

(psychomimetic) side effects, S(+)-ketamine, resting state fMRI, healthy volunteers
(psychomimetische) bijwerkingen, S(+)-ketamine, resting state fMRI, gezonde vrijwilligers

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Leiden, The Netherlands
Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

1. fMRI: whole-brain, voxel-wise RSN brain activity;

2. ASL: whole brain, voxel-wise CBF (millilitres of blood per 100g of tissue per minute) and CBF changes due to drug administration;

3. S(+)-ketamine and S(+)-norketamine plasma concentrations.

Secondary outcome

1. Visual Analogue Scale (VAS) to assess mood, alertness and calmness (Bond and Lader);

2. VAS to assess psychedelic effects (Bowdle);

3. VAS to assess heat pain stimulus.

Study description

Background summary

The aim of the study is to investigate the influence of S(+)-ketamine on the resting state fMRI in healthy volunteers. The study consists of 2 study days on which the volunteers receives S(+)-ketamine on one study day and placebo on the other study day in a randomised fashion. Before, during and after the infusion fMRI scans are made to look at resting state networks. Also before, during and after infusion S(+)-ketamine and S(+)-norketamine plasma concentrations and pharmacodynamic measurements will be obtained until approximately 3 hours after the start of the infusion.

Study objective

S(+)-ketamine influences resting state fMRI in a dose-dependent fashion.

Study design

2 study days with at least 3 days in between.

Intervention

The study consists of 2 study days on which the volunteers receives S(+)-ketamine on one study day and placebo (NaCl 0,9%) on the other study day in a randomised fashion. On the study days two intravenous cannulae (one cannula for infusion of the S(+)-ketamine or placebo, one cannula for blood sampling) will be placed. After the first fMRI scan has been made, the infusion of the study medication will start. 50 minutes after the start of the infusion a fMRI scan will be made, after which the infusion rate is increased. 50 minutes after the adaptation of the infusion rate, another fMRI scan will be performed. After this scan the infusion will be stopped. During the elimination phase another 2 fMRI scans will be made. Before, during and after infusion S(+)-ketamine and S(+)-norketamine plasma concentrations and pharmacodynamic measurements will be obtained at specified times until approximately 3 hours after the start of the infusion. Also side effects are measured with questionnaires.

Contacts

Public
Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301
Scientific
Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Eligibility criteria

Inclusion criteria

1. Healthy male;

2. Right handed subjects;

3. Naive to ketamine;

4. Between 18 to 45 years of age.

Exclusion criteria

1. Obesity (BMI > 30);

2. 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;

3. 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;

4. History of chronic alcohol or illicit drug use;

5. Unable to refrain from quinine containing products and grapefruit or grapefruit juice from 7 days prior to study start until the last study day;

6. 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;

7. Claustrophobia;

8. Allergy to study medications;

9. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-08-2010
Application type:	First submission

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
NTR-new	NL2358
NTR-old	NTR2465
Other	CME LUMC : P10.136
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A