Influence of ketamine on the brain.

No registrations found.

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

Summary

ID

NL-OMON28020

Source
NTR

Brief title
F-ket study

Health condition

Healthy volunteers

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: European union

Intervention

Outcome measures

Primary outcome

1. Functional MRI;

2. Pain scores;

3. Ketamine blood concentration.

Secondary outcome

1. Nausea and vomiting;

2. Psychomimetic side effects;

3. Saliva cortisol measurements.

Study description

Background summary

This study is conducted to evaluate the effect of ketamine on the brain and to link this to the pharmacokinetics and pharmacodynamics of the drug. A single blind placebo controlled trial will be performed and before, during and after the start of the infusion several functional MRI scans will be made. Furthermore, pain tests will be performed, blood samples will be taken and the presence of side effects will be evaluated during the whole study period.

Study objective

In this study we investigate the effect of ketamine on the brain. We hypothesize that ketamine influences brain areas involved in pain, cognitive function and psychosis.

The study aims are:

1. To investigate the effects of 2 plasma levels of S(+)-ketamine on fMRI activation patterns in healthy male volunteers;

2. To assess the feasibility of PK/PD-analyses for S(+)-ketamine-induced fMRI-activation patterns;

3. To investigate whether the subjective effects reported by volunteers can be linked to changes in fMRI activation patterns.

Study design

1. Functional MRI: Before, 1 and 2 hours after the start of the infusion and 20 and 120 minutes after the termination of the infusion;

2. Pain scores: Before infusion and every 20 minutes after the start of the infusion till the end of the study (approximately 4 hours);

3. Ketamine blood concentration: Blood samples will be taken at the same time points as the pain scores;

4. Nausea and vomiting: The presence of nausea will be determined at the same time points as the pain scores. Vomiting will be monitored during the whole study period;

5. Psychomimetic side effects: Side effects will be scored using a VAS scale at the same time points as the pain scores;

6. Saliva cortisol measurements: Saliva will be collected at the same time points as the pain scores.

Intervention

Every participant will have two study days:
1. Placebo administration;

2. Ketamine administration; ketamine will be given during 2 hours in two different concentrations. 20mg/70kg/h will be given the first hour and 40mg/70kg/h the second hour.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy right handed male subjects naive to ketamine between 18 to 45 years old.

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:	Non controlled trial
Masking:	Single blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-01-2011
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	NL2590
NTR-old	NTR2717
Other	MEC LUMC : P10.136
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A