Influence of ketamine on the brain.

Gepubliceerd: 26-01-2011 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28020

Bron
NTR

Verkorte titel
F-ket study

Aandoening

Healthy volunteers

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: European union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Functional MRI;
2. Pain scores;
3. Ketamine blood concentration.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2590
NTR-old	NTR2717
Ander register	MEC LUMC : P10.136
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A