The F-KET study.

Gepubliceerd: 12-08-2010 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON23425

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Leiden, The Netherlands
Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

2 study days with at least 3 days in between.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy male;

2. Right handed subjects;

3. Naive to ketamine;

4. Between 18 to 45 years of age.

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:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-08-2010
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	NL2358
NTR-old	NTR2465
Ander register	CME LUMC : P10.136
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A