The NorKet Study

Gepubliceerd: 27-05-2008 Laatst bijgewerkt: 18-08-2022

This study is designed to study the contribution and quantification of norketamine for its analgetic and psychomimetic effects

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

Samenvatting

ID

NL-OMON27795

Bron
NTR

Verkorte titel
N/A

Aandoening

Pharmacology
Pain
Healthy volunteers

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Anaesthesiology
Overige ondersteuning: TREND, Delft (NL)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Analgetic effect using a heat pain model

Toelichting onderzoek

Achtergrond van het onderzoek

The analgesic effects of S(+)-ketamine are known. S(+)-ketamine effects neurocognition. The contribution of its metabolite is however not known. With this study we are inducing the metabolism of S(+)-ketamine into norketamine. Heat pain is induced in healthy male volunteers, and VAS pain score will be obtained at the same time as blood samples are taken for pk/pd analysis. Also neurocognition is tested.

Doel van het onderzoek

This study is designed to study the contribution and quantification of norketamine for its analgetic and psychomimetic effects

Onderzoeksopzet

Two times admittance at our human laboratory for 1 day for ketamine treatment. After last visit no follow up

Onderzoeksproduct en/of interventie

The NorKet study consists of 2 studies: study A and study B. 15 volunteers will take part in study A. They will be admitted twice, with at least 3 weeks in between, at our human laboratory for 1 day during which measurements will take place. 5 days before each measurement day the volunteers will receive pretreatment with placebo on one occasion and rifampicine on the other occasion. During measurement day volunteers will be infused with S(+)-ketamine for 2 hours (the amount is based on weight, the infusion rate is 20 mg/h for a 70 kg subject). During and after infusion with S(+)-ketamine heat pain will be induced at several time points, the amount of pain is scored by VAS. Also arterial blood samples are taken for pk/pd analysis. 15 volunteers will take part in study B. They will be admitted 3 times, with at least 3 weeks in between, at our human laboratory for 1 day during which measurements will take place. 5 days before each measurement day the volunteers will receive pretreatment with placebo on 1 or 2 occasions and rifampicine on 1 or 2 other occasions. During measurement day volunteers will be infused with placebo (first occasion) or S(+)-ketamine (second and third occasion) for 2 hours (the amount is based on weight, the infusion rate is 20 mg/h for a 70 kg subject). During and after infusion with placebo or S(+)-ketamine heat pain will be induced at several time points, the amount of pain is scored by VAS. Also neurocognitive tests will be performed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy male subjects.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Obesity (BMI > 30);

2. Presence of medical disease (heart-, lung-, liver-, kidney-, neurologic disease; diabetes m.; pyrosis; diaphragmatic hernia);

3. Presence of psychiatric disease;

4. History of chronic alcohol or illicit drug use;

5. Allergy to study medications;

6. Color blindness;
7.
Use of contact lenses.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2008
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2008
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	NL1282
NTR-old	NTR1328
Ander register	TREND, Delft (NL); BSIK03016 : P08.075
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A