The NorKet Study

No registrations found.

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

Summary

ID

NL-OMON27795

Source
NTR

Brief title
N/A

Health condition

Pharmacology
Pain
Healthy volunteers

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Department of Anaesthesiology
Source(s) of monetary or material Support: TREND, Delft (NL)

Intervention

Outcome measures

Primary outcome

Analgetic effect using a heat pain model

Secondary outcome

Neurocognitive measurements(www.cnsvs.com) or;

Pharmacokinetic/pharmacodynamic analyses

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male subjects.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A