

Pharmacokinetic-pharmacodynamic modeling of S(+)-KETamine in healthy volunteers

Submission date 26/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/05/2019	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Pharmacokinetic-pharmacodynamic modeling of S(+)-KETamine in healthy volunteers

Acronym

KET study

Study objectives

We will investigate the relationship between S(+)-ketamine plasma concentrations and its analgesic effect to estimate the onset/offset times of ketamine and potency parameters for various analgesia tests. This will allow the safer administration of S(+) ketamine in clinical practice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Commissie Medische Ethiek on the 8th June 2006 (ref: WEC0604).

Study design

Randomised, placebo controlled, crossover, single blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Ketamine, analgesic

Interventions

Infusion of S(+)-ketamine or placebo.

There are three infusion schemes:

1. In four subjects there will be two 30-minute infusions of S(+)-ketamine, separated by 30 minutes of no-infusion (end of infusion is at $t = 90$ min)
2. In four subjects there will be five 10-minute infusions of S(+)-ketamine, all separated by 10 minutes of no-infusion (end-of infusion is at $t = 90$ min)
3. In four subjects there will be three 20-minute infusions of S(+)-ketamine, all separated by 20 minutes of no-infusion (end of infusions is at $t = 100$ min)

4. As 1., but now placebo (NaCl 0.9%) will be infused
5. As 2., but now placebo (NaCl 0.9%) will be infused
6. As 3., but now placebo (NaCl 0.9%) will be infused

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

S(+)-ketamine

Primary outcome measure

Analgesia and plasma concentration of ketamine.

Secondary outcome measures

Bowdle scale parameters.

Overall study start date

01/02/2007

Completion date

01/02/2008

Eligibility**Key inclusion criteria**

1. Healthy volunteers 18+

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

24

Total final enrolment

20

Key exclusion criteria

1. Obesity (Body Mass Index [BMI] more than 30)
2. Presence of medical disease (heart-, lung-, liver-, kidney-, neurological disease; diabetes m.; pyrosis; diaphragmatic hernia)
3. Presence of psychiatric disease
4. History of chronic alcohol or drug use
5. Allergy to study medications
6. Possibility of pregnancy
7. Lactation

Date of first enrolment

01/02/2007

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details

Department of Anaesthesiology

P.O. Box 9600

Leiden

Netherlands

2300 RC

Sponsor type

Hospital/treatment centre

Website

http://www.lumc.nl/english/start_english.html

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Government

Funder Name

Trauma Related Neuronal Dysfunction (TREND) Fund (Germany) - a consortium sponsored by the ministry of economic affairs (<http://www.crps.nl/>)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2009	09/05/2019	Yes	No