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

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 09/05/2019	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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 plasmaconcentrations and its analgesic effect to estimates 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).

Primary study design
Interventional

Study design
Randomised, placebo controlled, crossover, single blinded trial

Study type(s)
Treatment

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(s)
Analgesia and plasma concentration of ketamine.

Key secondary outcome(s)

Bowdle scale parameters.

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Healthy volunteers 18+

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

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
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2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

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

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