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

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

**Protocol serial number**
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 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).

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

## Primary study design
Interventional

## 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
Netherlands
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 |