

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

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

**Contact name**  
Prof Albert Dahan

**Contact details**  
Leiden University Medical Centre (LUMC)  
Department of Anesthesiology  
P.O. Box 9600  
Leiden  
Netherlands  
2300 RC  
+31 (0)71 526 2301  
a.dahan@lumc.nl

## 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 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

## **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?
<a href="#">Results article</a>	results	01/10/2009	09/05/2019	Yes	No