

# Feasibility and pharmacokinetics of nebulized S-ketamine inhalation in healthy adults the NebuKet study

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON23977

### Source

NTR

### Brief title

NebuKet

### Health condition

- ketamine
- nebulization
- pharmacokinetics
- analgesia
- side effects

## Sponsors and support

**Primary sponsor:** anesthesiology department of LUMC

**Source(s) of monetary or material Support:** self-financing research

## Intervention

## Outcome measures

### Primary outcome

safety of procedure

### Secondary outcome

analgesia, pharmacokinetics and hemodynamic effects (Blood pressure, cardiac output, heart rate)

## Study description

### Background summary

The aim of this study is to investigate the efficacy and safety of nebulizing S-ketamine. Three different doses of nebulized S-ketamine will be administered. Arterial blood samples will be taken to measure pharmacokinetic effect. The analgesic effect will be measured by two different pain tests (pressure and electrical test). Side effects will be evaluated by two questionnaires (Bowdle, and Bond&Lader)

### Study objective

- Hypothesis#1 efficacy

We hypothesize that a quick onset, and a predictable dose-response, good adjustability of analgesia can be achieved with inhaled ketamine.

Hypothesis#2 safety

Inhalation of nebulized ketamine might lead to a fast onset of analgesia, with limited adverse events.

### Study design

Analgesia: before nebulization, 18, 30, 60 and 80 minutes  
after start of nebulization, pain relief to pressure pain will be studied

pharmacokinetics: arterial blood samples (3 ml per sample) for ketamine and norketamine will be taken before nebulization/iv infusion and at specific time points during and after inhalation and iv treatment.

- Hemodynamics: Continuous cardiopulmonary monitoring

-Side effects will be inquired before start of nebulization, just after and every 20 minutes after nebulization. Side effects will be measured using visual analog scales ranging from 0 to 10 cm of the Bowdle and Bond & Lader questionnaires.

## **Intervention**

nebulizing ketamine

## **Contacts**

### **Public**

Leiden University Medical Center (LUMC),  
Department of Anesthesiology,  
P.O. Box 9600  
Albert Dahan  
Albinusdreef 2  
Leiden 2300 RC  
The Netherlands  
+31 (0)71 5262301

### **Scientific**

Leiden University Medical Center (LUMC),  
Department of Anesthesiology,  
P.O. Box 9600  
Albert Dahan  
Albinusdreef 2  
Leiden 2300 RC  
The Netherlands  
+31 (0)71 5262301

## **Eligibility criteria**

### **Inclusion criteria**

men/women 18-39years BMI <30kg/m<sup>2</sup>

### **Exclusion criteria**

pulmonary disease, hypertensin, liver/renal disease, neurological disorders diaphragmatic hernia/pyrosis, (history of) psychiatric or neurological disease, pregnancy/lactation, allergy to

study medication, (history of) illicit drug use/alcoholism; concurrent participation in another trial

## Study design

### Design

|                     |                         |
|---------------------|-------------------------|
| Study type:         | Interventional          |
| Intervention model: | Other                   |
| Allocation:         | Non controlled trial    |
| Masking:            | Open (masking not used) |
| Control:            | N/A , unknown           |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Recruiting  |
| Start date (anticipated): | 12-08-2015  |
| Enrollment:               | 20          |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 11-08-2015       |
| 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  | NL5210                   |
| NTR-old  | NTR5358                  |
| Other    | NL53147.058.15 : P15.107 |

## Study results