

# pharmacokinetic-pharmacodynamic modeling of S(+)-ketamine in fibromyalgia

Published: 10-09-2008

Last updated: 06-05-2024

To test the hypothesis that ketamine has a modulatory effect on fibromyalgia

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	General system disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32088

### Source

ToetsingOnline

### Brief title

fibro-ketstudy

### Condition

- General system disorders NEC
- Muscle disorders
- Neuromuscular disorders

### Synonym

fibromyalgia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van Economische Zaken;TREND;Delft (NL); BSIK03016

## Intervention

**Keyword:** analgesic therapy, fibromyalgia, ketamine, pain

## Outcome measures

### Primary outcome

painscores on a visual analogue scale (VAS)

quality of life: fibromyalgia impact questionnaire (FIQ)

### Secondary outcome

Furthermore this study investigate the pharmacokinetics and pharmacodynamics of (S+)-ketamine in subanaesthetic doses in fibromyalgia.

## Study description

### Background summary

The treatment of Complex Regional Pain Syndrome type 1 (CRPS) with S(+) ketamine showed good pain relief for weeks. Experimental pain responses returned to baseline almost immediately after the end of ketamine infusion. This suggests that ketamine might have modulatory effect on chronic pain in general.

### Study objective

To test the hypothesis that ketamine has a modulatory effect on fibromyalgia

### Study design

open treatment for two hours, total study duration five hours

### Intervention

ketamine infusion

### Study burden and risks

mild temporarily occurrence of side effects such as vivid dreams, high feeling,

and nausea.

## Contacts

### Public

Leids Universitair Medisch Centrum

Albinusdreef 2  
2333 ZA Leiden  
NL

### Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2  
2333 ZA Leiden  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

fibromyalgia patients

### Exclusion criteria

Obesity (BMI > 30);

Presence of psychiatric disease;

History of chronic alcohol or drug use;

Known allergy to study medications;  
Possibility of pregnancy; and  
Lactation.

## Study design

### Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2009
Enrollment:	12
Type:	Actual

### Medical products/devices used

Product type:	Medicine
Brand name:	Ketanest
Generic name:	S(+)-ketamine
Registration:	Yes - NL outside intended use

## Ethics review

Approved WMO	
Date:	10-09-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	

Date:	16-03-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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
EudraCT	EUCTR2008-004002-14-NL
CCMO	NL23851.058.08