

# Treatment of Complex Regional Pain Syndrome type I; A randomised, single-blind, placebo-controlled study with multiple rounds of S(+)-ketamine infusions.

No registrations found.

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

## Summary

### ID

NL-OMON21045

### Source

NTR

### Brief title

The KetKet study, pilot

### Health condition

Complex Regional Pain Syndrome type I (CRPS type I)  
Complex Regionaal Pijn Syndroom type I (CRPS type I)

## Sponsors and support

**Primary sponsor:** Leiden University Medical Center (LUMC), Department of Anesthesiology  
**Source(s) of monetary or material Support:** TREND, Delft

## Intervention

## Outcome measures

### Primary outcome

- Pain scores (NRS)
- Allocation scores patients, whether they received S(+)-ketamine or placebo.

### Secondary outcome

- Occurrence of side effects
- Presence of CRPS type I diagnosis after treatment.

## Study description

### Background summary

The treatment of Complex Regional Pain Syndrome type I (CRPS) with S(+)-ketamine showed good pain relief for weeks. However, in most patients, the pain returns to baseline levels. Open label studies suggest a longer duration of pain relief when ketamine is administered more than once. In this randomised, single-blind, placebo-controlled pilot study, we administer S(+)-ketamine once or twice to test whether pain relief is prolonged with multiple infusions of S(+)-ketamine.

### Study objective

Multiple rounds of S(+)-ketamine infusions will give more profound and prolonged pain relief compared to a single infusion of S(+)-ketamine.

### Study design

- Baseline measurements before first admission.
- Measurements, on average 3 times a day, during admissions.
- Weekly measurements between and after admissions, until baseline is reached, afterwards on average monthly measurements.
- Follow-up up to 52 weeks from first admission.

### Intervention

Patients are randomised into 3 groups.

Admissions will take place in week 1 and 4 or week 1 and 13 of the study. All patients are admitted twice for 5 days, during which they will receive intravenous S(+)-ketamine or active placebo midazolam, both in an increasing subanesthetic dose based on weight.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

1. CRPS type I diagnosis according to the IASP-criteria;
2. NRS spontaneous pain score of 5 or higher;
3. Age is between 18 and 70 years;
4. Patients must give a written informed consent.

### **Exclusion criteria**

1. Patients who are not able to give informed consent;

2. Patients suffering from other syndromes/diseases interfering with pain ratings;
3. Patients who previous have had ketamine continuous infusion;
4. Patients with co-morbidity such as:  
kidney disease, severe liver disease, nerve damage in the affected area, increased intracranial pressure, infectious disease, epilepsy, a psychiatric illness, thyroid disease, cancer, cardiac disease, pulmonary disease, severe or uncontrolled hypertension, aneurysm, glaucoma, history of cerebral vascular accident (CVA) < 1 year;
5. Patients who are pregnant.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-11-2008
Enrollment:	30
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	20-11-2008
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	NL1479
NTR-old	NTR1550
Other	TREND, Delft (NL); BSIK03016 : P08.106
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A