# Treatment of Complex Regional Pain Syndome type 1: a randomised, double-blind, placebo-controlled study with S(+)-ketamine.

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S(+)-ketamine reduces pain in patients with Complex Regional Pain Syndome type 1 having symptoms shorter than 6 months and longer than 3 years.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22578

**Bron**
Nationaal Trial Register

**Verkorte titel**
N/A

**Aandoening**

Complex Regional Pain Syndome type 1 (CRPS 1)

### Ondersteuning

**Primaire sponsor:** Leiden University Medical Center, dep. Anaesthesiology
**Overige ondersteuning:** Ministry of Economic Affairs, BSIK03016

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Painreduction measured by numerical rating scale (0 no pain, 10 worst imaginable pain).

# Toelichting onderzoek

### Achtergrond van het onderzoek

The treatment of Complex Regional Pain Syndrome type 1 (CRPS) is characterised by a trial and error approach. Until now no single mechanism in the natural course of CRPS is known that can be treated directly. In neuropathic pain studies ketamine (=NMDA receptor antagonist) in subanaesthetic doses has proven its efficacy. In few CRPS studies patients benefited from the treatment with ketamine i.v. However, these studies were not double-blind controlled. The present study is directed at the continuous intravenous administration of sub-anaesthetic doses of S(+)-ketamine on a clinical patient basis to evaluate the role of the NMDA receptor activation in the pathophysiology of CRPS (proof of concept study). For clinical interest an intent-to-treat analysis will be performed as well. Furthermore this study investigate the pharmacokinetics and pharmacodynamics of (S+)-ketamine in subanaesthetic doses.

### Doel van het onderzoek

S(+)-ketamine reduces pain in patients with Complex Regional Pain Syndome type 1 having symptoms shorter than 6 months and longer than 3 years.

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

Subjects are assigned to receive either intravenous (S+)-ketamine or placebo.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients will be male or female adult patients with a clinical diagnosis of CRPS 1 who are referred to the pain centre outpatients' clinic of the department of Anaesthesiology at the LUMC.

1. Patients should fulfill the diagnostic criteria of the consensus report of CRPS 1:

a. continuing pain, allodynia or hyperalgesia, in which the pain is disproportionate to any inciting event,

b. evidence at some time of edema, changes in skin blood flow or abnormal sudomotor activity in the region of the pain and

c. no condition that would otherwise account for the degree of pain and dysfunction.

2. Patients must report a VAS-spontaneous pain score of 5 cm or higher.

3. Patients’ age is between 18 and 70 years.

4. Onset of symptoms must be shorter than 6 months or longer than 3 years before inclusion.

5. Patients should give a written informed consent.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Patients suffering from other pain syndromes, interfering with pain ratings.

3. Patients suffering from other syndromes interfering with pain ratings.

4. Patients suffering from a kidney and/or severe liver disease.

5. Patients suffering from nerve damage in the affected area.

6. Patients with an active infection.

7. Patients with high intracranial pressure.

8. Patients with epilepsy.

9. Patients with a psychiatric illness.

10. Patients with thyroid disease.

11. Patients with cancer.

12. Patients with cardiac disease.

13. Patients with pulmonary disease.

14. Patients with glaucoma.

15. Patients with a history of cerebral vascular accident (CVA).

16. Patients who are a pregnant.

17. Strong-opioid consumption (step one and two of the WHO pain ladder is allowed).

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-12-2005 |
| Aantal proefpersonen: | 60 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 25-11-2005 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL466 |
| NTR-old | NTR507 |
| Ander register | : LUMC P05.100; Min. of Econ. Aff., BSIK03016 |
| ISRCTN | ISRCTN38472359 |

# Resultaten

### Samenvatting resultaten

N/A