

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

<b>Submission date</b> 09/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/08/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

### Study objectives

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

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Received from local medical ethics committee

### Study design

Randomised double blind placebo controlled parallel group trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Complex regional pain syndrome type 1 (CRPS I)

### Interventions

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

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

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

### Secondary outcome measures

Secondary aims of the study deal with:

1. The role of NMDA receptor activation in the autonomic and motor features of CRPS
2. To establish the endurance of ketamine on the impairments of CRPS
3. To study the pharmacokinetics and pharmacodynamics of ketamine in subanaesthetic doses
4. To establish data for future pragmatic studies on ketamine iv in patients with CRPS on the levels of disability and safety

**Overall study start date**

01/12/2005

**Completion date**

01/12/2007

## **Eligibility**

**Key inclusion criteria**

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:
  - 1.1. Continuing pain, allodynia or hyperalgesia, in which the pain is disproportionate to any inciting event
  - 1.2. Evidence at some time of edema, changes in skin blood flow or abnormal sudomotor activity in the region of the pain
  - 1.3. 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. Patient's 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

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

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)

**Date of first enrolment**

01/12/2005

**Date of final enrolment**

01/12/2007

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Leiden University Medical Center**

Leiden

Netherlands

2300 RC

## **Sponsor information**

**Organisation**

Leiden University Medical Centre (Netherlands)

**Sponsor details**

Department of Anaesthesiology

P.O. Box 9600

Leiden

Netherlands

2300 RC

**Sponsor type**

Hospital/treatment centre

ROR

<https://ror.org/027bh9e22>

## Funder(s)

### Funder type

Government

### Funder Name

Ministry of Economic Affairs (Netherlands)

### Alternative Name(s)

Ministry of Economic Affairs, Netherlands Ministry of Economic Affairs, EZ

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Netherlands

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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		Yes	No