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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22578

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Complex Regional Pain Syndome type 1 (CRPS 1)

Sponsors and support

Primary sponsor: Leiden University Medical Center, dep. Anaesthesiology
Source(s) of monetary or material Support: Ministry of Economic Affairs, BSIK03016

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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 i.v. in patients with CRPS on the levels of disability and safety.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

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:

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.

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2005
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	25-11-2005
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	NL466
NTR-old	NTR507
Other	: LUMC P05.100; Min. of Econ. Aff., BSIK03016
ISRCTN	ISRCTN38472359

Study results

Summary results
N/A