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.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21045

Source
Nationaal Trial Register

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

- Occurence 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 adminster 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

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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