Treatment of Complex Regional Pain Syndrome type I;A randomised, double-blind, placebo-controlled study with multiple rounds of S(+)-ketamine infusions (The Ket Ket Study)

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON31841

Source
ToetsingOnline

Brief title
KetKet Study

Condition

- Peripheral neuropathies

Synonym
CRPS-1; chronic pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: TREND;delft

Intervention

Keyword: CRPS-1, Pain, Treatment

Outcome measures

Primary outcome

The primary aim of this study is to evaluate the effect of two consecutive

infusions of S(+)-ketamine in patients with CRPS-I on pain relief. The design

of the study is prospective, randomised, double-blind and placebo-controlled.

Secondary outcome

• To establish the effect of S(+)-ketamine on sensory, autonomic and motor

disturbances in

CRPS-1 patients.

• To establish the side effect profile of multiple S(+)-ketamine infusions.

Study description

Background summary

Treatment of CRPS-1 has proven to be extremely difficult. Since the cause of CRPS-1 is unknown there is no direct action against the causative agent possible. Many treatment modalities have been proposed, alone or in combination, such as physiotherapy, oral medication (incl. analgesics, antidepressants, antioxidants), sympathetic block, and epidural analgesia. Treatment remains largely empirical and symptomatic, with frequently only marginal effectiveness. Recently investigations focused on the use of ketamine in CRPS-1.

Study objective

Primary aim:
The primary aim of this study is to evaluate the effect of two consecutive infusions of S(+)-ketamine in patients with CRPS-I on pain relief. The design of the study is prospective, randomised, double-blind and placebo-controlled.

Secondary aims of this study are:
• To establish the effect of S(+)-ketamine on sensory, autonomic and motor disturbances in
CRPS-1 patients.
• To establish the side effect profile of multiple S(+)-ketamine infusions.

Study design

5.1 Design of the pilot study (see also Table 1)
The pilot study will consist of 5 groups:
• Group 1: patients will be admitted in week 1 and week 4 and will receive S(+)-ketamine on
both occasions. The total study duration will be 52 weeks.
• Group 2: patients will be admitted in week 1 and week 13 and will receive S(+)-ketamine
on both occasions. The total study duration will be 52 weeks.
• Group 3: patients will be admitted in week 1 and week 13. In week 1 patients will receive
an active placebo and in week 13 S(+)-ketamine. The total study duration will be 52 weeks.
• Group 4: historical control-patients who participated in the previous clinical trial (P05.100).
They received a single S(+)-ketamine infusion at week 1. The study duration was in total
12 weeks.
• Group 5: historical control-patients who participated in the previous clinical trial (P05.100).
They received a single placebo (saline) infusion at week 1. The study duration was in total
12 weeks.
Patients in Groups 1 to 3 will be admitted twice for 5 days, during which a continuous intravenous infusion will take place with S(+)-ketamine or active placebo.
Because of different weeks of admission, the study will be performed single-blinded.
Table 1 shows the schematic overview of the pilot design.

5.2 Clinical trial design (see also Table 2)
Patients will be recruited and randomized into 2 groups. Both groups will be admitted twice for 5 days, during which intravenous continuous infusions will

take place with S(+)-ketamine or (active) placebo.

• Group 1 will be admitted in week 1 and week x (week x will be determined from the pilot
study) and will receive S(+)-ketamine on both occasions.
• Group 2 will be admitted in week 1 and week x and will receive S(+)-ketamine in week 1
and (active) placebo in week x.

The first infusion will be performed single-blinded and the second infusion will be performed double-blinded. Because we expect longstanding positive effects of S(+)-ketamine on pain scores, the total duration of the study will be 52 weeks.

Study burden and risks

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients are diagnosed with CRPS-1 according to the IASP-criteria;
• Patients must report a NRS spontaneous pain score of 5 or higher;
• The age of the patient is between 18 and 70 years;
• Patients must give a written informed consent;

Exclusion criteria

• Patients who are not able to give informed consent;
• Patients suffering from other syndromes/diseases interfering with pain ratings;
• Patients who have had previous ketamine continuous infusion;
• 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;
• Patients who are pregnant.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Will not start

Start date (anticipated):	01-09-2008
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Dormicum
Generic name:	midazolam
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Ketanest-S
Generic name:	S(+)-ketamine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-06-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2008-003693-17-NL
CCMO	NL23609.058.08