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

Submission date	Recruitment status	[ ] Prospectively registered
09/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/08/2009	Musculoskeletal Diseases	

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

NTR507; LUMC P05.100; Min. of Econ. Aff., BSIK03016

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
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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?
Results article	results	01/10/2009		Yes	No