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Percutaneous sympathetic blockade in complex regional pain syndrome type 1: a prospective clinical investigation on predictors of sympatheticaly maintained pain

Submission date
07/06/2006

Recruitment status
No longer recruiting

Registration date
07/06/2006

Overall study status
Completed

Last Edited
02/05/2019

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
BSIK03016

Study information

Scientific Title
Percutaneous sympathetic blockade in complex regional pain syndrome type 1: a prospective clinical investigation on predictors of sympatheticaly maintained pain

Acronym
SYMBLOC

Study objectives
The cold phenotype of CRPS1 is associated with a better response to percutaneous sympathetic blockade as opposed to the warm type of CRPS1.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Complex regional pain syndrome type 1 (CRPS I) (Causalgia)

Interventions
Upper extremity CRPS-1: percutaneous blockade of stellate ganglion at C7 with one single injection of bupivacaine 0.25%.

Lower extremity CRPS-1: percutaneous blockade of lumbar sympathetic chain at L3 with a single injection of bupivacaïne 0.25%.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bupivacaine

Primary outcome measure
Pain relief in the first week after blockade as measured three times daily in a pain diary where, 0 = no pain and 10 = worst imaginable pain

Secondary outcome measures
The following predictors of pain relief after sympathetic blockade will be measured:
1. Pain intensity on an NRS scale of 0 to 10
2. Subjective and objective skin temperature
3. Hyper- and hypo-esthesia
4. Allodynia
5. Hyper- and hypo-algesia
6. The presence of dystonia
7. Tremor and myoclonus

Overall study start date
10/04/2006

Completion date
10/04/2008

Eligibility

Key inclusion criteria
Adult (18 years or more) male or female patients with CRPS1 as diagnosed by International Association for the Study of Pain (IASP) criteria, with a duration of 12 months or less with moderate to severe pain (mean numerical rating scale [NRS] of more than 4 in the previous week as measured three times daily in a pain diary where, 0 = no pain and 10 = worst imaginable pain) and one extremity involved.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

124

Total final enrolment
49

Key exclusion criteria
1. Patients of less than 18 years of age
2. The existence of significant impairment of blood coagulation or the use of oral anticoagulant medication
3. Patients suffering from diabetic polyneuropathia
4. Patients who are unlikely to comply with study requirements
5. Pregnant women
6. CRPS1 with a duration of more than 12 months

Date of first enrolment
10/04/2006

Date of final enrolment
10/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Hospital Maastricht (AZM)
Maastricht
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6202 AZ

Sponsor information

Organisation
Academic Hospital Maastricht (AZM) and Dutch Consortium for Research on Trauma Related Neuronal Dysfunction (TREND)

Sponsor details
P.O. Box 5800
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Sponsor type
University/education

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Government

Funder Name
Ministry of Economic Affairs (BSIK03016)

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	01/01/2012	02/05/2019	Yes	No