

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

Submission date 07/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/05/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 sympathetically 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 bupivacaine 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

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

Netherlands

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