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The effect of intrathecal methylprednisolone on features of central sensitisation in patients with chronic complex regional pain syndrome (CRPS) type one

Submission date 23/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2006	**Overall study status** Completed	
Last Edited 04/06/2019	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J J van Hilten

Contact details
Leiden University Medical Centre
Department of Neurology
Postzone K-05Q
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 2895
j.j.van_hilten.neurology@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BSIK03016; NTR61

Study information

Scientific Title
The effect of intrathecal methylprednisolone on features of central sensitisation in patients with chronic complex regional pain syndrome (CRPS) type one

Acronym
IMAC (Intrathecal Methylprednisolone And CRPS)

Study objectives
Intrathecal methylprednisolone reduce the features of central sensitisation in patients with complex regional pain syndrome (CRPS) type one having symptoms longer than six months and shorter than six years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee

Study design
Randomised, placebo-controlled, double-blind, parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic complex regional pain syndrome type 1 (CRPS I)

Interventions
In all patients a lumbar puncture will be performed. After a lumbar puncture 5 ml of fluid is removed for cytologic and biochemical tests. An additional 5 ml of fluid will be removed for the measurement of the level of cytokines. Then 60 mg of Depo-medrol® (methylprednisolone acetate) or placebo is injected. For patients whose pain is located in an arm the table will be

tilted into the head-down position immediately after the intrathecal injection to allow the injected material to spread to the upper thoracic canal. Patients with symptoms in the lower extremities are kept in a horizontal position.

Outcomes will be assessed six weeks after the intervention.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methylprednisolone acetate

Primary outcome measure
The severity of spontaneous pain is evaluated through a 10 cm visual analogue scale (0 cm represents no pain, 10 cm represents the worst imaginable pain). This will be filled in at home in a diary. Primary outcome is pain relief at six weeks.

Secondary outcome measures
1. Sensory assessments:
1.1. The nature of the pain is assessed by means of the neuropathic pain scale developed by Galer which consists of several visual analogue scales for different kinds of pain. Also a McGill Pain Questionnaire will be administered
1.2. Hyper- and hypo-esthesia and allodynia will be tested using Von Frey hairs
1.3. Pain and temperature perception thresholds (Temperature Sensory Assessment using the Medoc TSA II Neurosensory Analyser). A thermode will be placed on the volar side of the wrist or dorsal side of the foot
1.4. Somatosensory evoked potentials
2. Autonomic assessments:
2.1. Skin temperature of affected and contralateral extremity and midsternal
2.2. The difference in volume between the affected and contralateral extremity is assessed by a volumeter as a measure for edema. This instrument measures the amount of water that is displaced by the immersed body part
2.3. Pulse transit time (the time the pulse wave takes to travel from heart to finger) as a measure of peripheral vessel resistance
3. Motor assessments:
3.1. Patients will be evaluated for the presence and severity dystonia, myoclonus and tremor (none, intermittent, continuous)
3.2. Range of motion will be assessed using a universal goniometer
3.3. In those patients in which this can be evaluated, movement velocity of repetitive fingertaps will be objectively quantified
3.4. In those patients in which this can be evaluated, proprioceptive reflexes will be assessed using a wrist pertubator
4. Disability:
4.1. Patients will be asked to mark the change in function of the affected hand or foot on a scale from one to seven (one = maximal worse, four = no change, seven = maximal better)
4.2. Radboud skills questionnaire, walking stairs questionnaire and questionnaire rising and sitting down will be administered
4.3. Participation and global health will be assessed using the Short Form (SF-36)questionnaire,

EuroQol 5D questionnaire, Inventarisatielijst Sociale Betrekkingen (ISB) and Impact on Participation and Autonomy (IPA)
5. (Serious) adverse events

Overall study start date
01/08/2005

Completion date
01/02/2008

Eligibility

Key inclusion criteria
Patients will be male or female, outpatients aged 18 to 75 years, with a clinical diagnosis of CRPS who are referred to the Leiden University Medical Centre (LUMC):
1. At onset patients must fulfill the criteria for CRPS I. These criteria include:
1.1. The combination of continuing pain
1.2. Allodynia or hyperalgesia
1.3. Rendering the pain disproportionate to any inciting event
1.4. Evidence at some time of oedema
1.5. Changes in skin blood flow
1.6. Abnormal sudomotor activity in the region of the pain
1.7. Absence of a condition which would otherwise account for the degree of pain and dysfunction
2. When entering the study patients must suffer from symptoms and signs indicative of central sensitisation (continuing pain, hyperalgesia and/or allodynia)
3. Patients must have symptoms for more than six months and shorter than six years
4. Use of pain medication must have been stable in the previous four weeks
5. Patients must be willing and able to give informed consent according to the national requirements
6. Patients must report spontaneous pain of at least 5 cm on a visual analogue scale (0 cm represents no pain, 10 cm represents the worst imaginable pain)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Total final enrolment
42

Key exclusion criteria
1. Patients are excluded if they can obtain satisfactory relief of symptoms with conventional treatments such as non-steroidal anti-inflammatory drugs (NSAIDs) or paracetamol
2. Patients using oral anticoagulant medication or having an impaired blood coagulation for other reasons
3. Patients suffering from diabetes mellitus
4. Patients with an immunocompromised state
5. Patients with an acute infection
6. Patients with an intracranial space occupying lesion
7. Patients with a thrombocytopenia of less than 50 x 10^9/l
8. Patients with clinically significant psychiatric illness
9. Patients who have a history of alcohol or drug abuse within the past year
10. Patients with a known hypersensitivity to (methyl)prednisolone
11. Patients who are unlikely to comply with study requirements or have a history of poor compliance to medical regimens or study requirements
12. Patients who have received an experimental treatment within the last month
13. Pregnant, nursing women and females of childbearing potential not using oral contraceptives or a medically recognised mechanical means of contraception
14. Patients involved in legal proceedings (claiming compensation for the CRPS I)

Date of first enrolment
01/08/2005

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
Department of Neurology
P.O. Box 9600

Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Government

Funder Name
Ministry of Economic Affairs (The 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	01/05/2010	04/06/2019	Yes	No