The effect of intrathecal methylprednisolone on features of central sensitization in patients with Chronic Complex Regional Pain Syndrome Type 1.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20155

Source
NTR

Brief title
IMAC (Intrathecal Methylprednisolone And CRPS; CRPS is an abbrevation for complex regional pain syndrome)

Intervention

Outcome measures

Primary outcome

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 6 weeks.

Secondary outcome

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 Mc Gill Pain Questionnaire will be administered;

1.2 Hyper- and hypoesthesia 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 1 to 7 (1=maximal worse, 4=no change, 7=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;

4.4 questionnaire, EuroQol 5D, Inventarisatielijst Sociale Betrekkingen (ISB) and Impact on Participation and Autonomy (IPA);

5. (Serious) adverse events

Study description

Background summary

Primary objective:
to compare the efficacy of intrathecal methylprednisolone (ITM) to placebo in reducing the features of central sensitization in patients with CRPS I having symptoms longer than 6 months and shorter than 6 years.

Secondary objective:

to evaluate the safety of ITM in this population and
to evaluate the effect of ITM on the occurrence of post-dural puncture headache.
This study is part of the TREND project. TREND is an acronym for Trauma RElated Neuronal Dysfunction.

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.

Outcome will be assessed 6 weeks after the intervention.

Study objective

Intrathecal methylprednisolone reduce the features of central sensitization in patients with complex regional pain syndrome type 1 having symptoms longer than 6 months and shorter than 6 years.

Intervention

Subjects are assigned to receive either intrathecal 60 mg methylprednisolone acetate or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

Patients will be male or female, outpatients aged 18 - 75 year, with a clinical diagnosis of CRPS who are referred to the LUMC .

1. At onset patients must fulfill the criteria for CRPS I. These criteria include the combination of continuing pain, allodynia or hyperalgesia, rendering the pain disproportionate to any inciting event, evidence at some time of edema, changes in skin blood flow, or abnormal sudomotor activity in the region of the pain, 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 sensitization (continuing pain, hyperalgesia and/or allodynia);

3. Patients must have symptoms for more than 6 months and shorter than 6 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).

Exclusion criteria

1. Patients are excluded if they can obtain satisfactory relief of symptoms with conventional treatments such as 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 50x109/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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-08-2005
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-07-2005
Application type:	First submission

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
NTR-new	NL35
NTR-old	NTR61

Register	ID
Other	: Ministry of Economic Affairs, number BSIK03016
ISRCTN	ISRCTN01838427

Study results

Summary results
N/A