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

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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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20155

Bron
Nationaal Trial Register

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-08-2005
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL35
NTR-old	NTR61
Ander register	: Ministry of Economic Affairs, number BSIK03016
ISRCTN	ISRCTN01838427

Resultaten

Samenvatting resultaten
N/A