# Prednisolone or DMSO for the treatment of CRPS-1 (post-traumatic dystrophy).

Gepubliceerd: 25-01-2011 Laatst bijgewerkt: 18-08-2022

There is no difference between treatment with DMSO and prednisolone in reduction of inflammatory signs and symptoms as measured with a validated compound score (ISS) on the severity of CRPS-1.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27005

**Bron**
NTR

**Verkorte titel**
Prednisolone versus DMSO

**Aandoening**

Complex Regional Pain Syndrome type 1
Complex Regionaal Pijn Syndroom type 1, post-traumatische dystrofie

### Ondersteuning

**Primaire sponsor:** Ministery of Economics, (BSIK03016)
**Overige ondersteuning:** Ministery of Economics, (BSIK03016)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Reduction of inflammatory signs and symptoms measured by the Impairment Level Sum

Score (ISS). The ISS is a validated measurement index consisting of pain, temperature, volume and range of motion differences between the affected and the contra-lateral extremity, whereby a difference score of 5 points or more between the treatment groups or compared to baseline is considered clinically relevant.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Background of the study:

Complex regional pain syndrome type 1 (CRPS-1) is a painful and disabling condition which can develop after trauma, such as a wrist fracture, distortion or operation, but can also develops without preceding incident. CRPS-1 is characterized by pain and sensory abnormalities, oedema and sudomotor dysfunction, colour change, limited range of motion and autonomic disturbances (for example, excessive sweating of the affected limb). For the Netherlands an estimated incidence rate for CRPS-1 is 26.2 per 100.000 person years. The progression of the disease is variable, and may lead, despite of treatments to permanent disability. Although various possible pathophysiological mechanisms have been described in literature, thus far, no single mechanism can be pinpointed to explain the complexity of symptoms exhibited in CRPS-1. However, inflammatory processes can explain a majority of signs and symptoms in CRPS-1. Treatment of CRPS-1, therefore, focuses on inhibition of these inflammatory processes, using the free radical scavenger DMSO in the Dutch clinical situation or treatment with corticosteroids in the Netherlands as well as in other countries. However, these therapies are based on low levels of scientific evidence. Furthermore, tolerance is not well described for both treatment options and CRPS-1.

Objective of the study:

In this trial we will study if treatment with oral corticosteroids or DMSO is effective in decreasing signs and symptoms of CRPS-1. Tolerance of the treatment options and effects on different subtypes of CRPS-1 patients will be evaluated as well.

Study design:

The study is designed as a prospective, randomised, parallel (double dummy), double blind design.

Study population:

Patients with CRPS-1 according to the clinical Budapest criteria will be asked to participate.

Intervention:

Patients will be treated with DMSO cream 5 times a day, combined with placebo oral medication during a period of 22 days (tapering period included) or with prednisolone 60 mg/day during 2 weeks, where after tapered, combined with placebo cream 5 times a day.

Primary study parameters/outcome of the study:

As primary outcome the ISS score will be evaluated, which is a compound score consisting of seperate scores based on signs and symptoms that are of importance for patients with CRPS-1. The score goes from 5 till 50 and a clinical relevant result is obtained when the ISS decreases 5 points from baseline or compared to the other treatment group.

Secundary study parameters/outcome of the study:

1. Safety of treatment with high dose corticosteroids and tolerance of both therapies is assessed by questionnaires and clinical evaluation;

2. Reduction of inflammatory markers in urine and blood plasma compared to baseline and between groups;

3. Reduction of sensory, autonomic and motor disturbances as measured by the McGill Pain Questionnaire, Pain Box scores, Range of motion, volumetric and temperature assessments compared to baseline and the DMSO group compared to the corticosteroid group;

4. Increase of functional status of the affected extremity as measured by the Walking Ability Questionnaire for lower extremity CRPS-1, and Radboud Skills Questionnaire for upper extremity CRPS-1 compared to the baseline and between the groups;

5. Improvement of health related quality of life as measured by the SF-36 to the baseline and between the groups.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The burden on the patients exists mainly of time it will consume. Patients are asked to visit the hospital 5 times for the measurements described above. Furthermore, they will fill out questionnaires four times, each time approximately one hour time and they will keep a pain diary for 5 weeks which will take them 5 to 15 minutes a day. The risk of this trial consists of side effects known by the use of corticosteroids. Rare, but severe side effects are femur and humerus head necrosis, neurological disturbances and trombo-embolic events.

**Doel van het onderzoek**

There is no difference between treatment with DMSO and prednisolone in reduction of inflammatory signs and symptoms as measured with a validated compound score (ISS) on the severity of CRPS-1.

**Onderzoeksopzet**

The investigator will perform the assessments. Measurements will take place prior to, at the end of treatment (after 4 weeks), 6 and 9 weeks after starting the trial according to the TREND-studies measurement protocol.

**Onderzoeksproduct en/of interventie**

Group A:

Prednisolone 60 mg/day during 2 weeks, where after tapered every 4 days with 20 mg, combined with placebo cream 5 times a day.

Group B:

DMSO cream 50% 5 times a day, combined with placebo oral medication during a period of 22 days (tapering period included).

# Contactpersonen

## Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

CRPS-1 according to the Budapest criteria for clinical diagnosis.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18;

2. Not being able to give informed consent;

3. Another (2nd) chronic pain syndrome, interfering with pain ratings;

4. Another syndrome interfering with functional tests;

5. CRPS-1 in both hands or feet;

6. Known kidney insufficiency or severe liver disease;

7. Active infection;

8. Mental retardation;

9. Psychiatric abnormality;

10. Malignant disease;

11. Pregnancy;

12. Established severe osteoporosis;

13. Established gastric ulcera;

14. Hypersensitivity or allergy to prednisolone or DMSO;

15. Use of anti-coagulantia;

16. Myasthenia gravis;

17. Previous use of DMSO for a period longer than 1 month.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-10-2010 |
| Aantal proefpersonen: | 76 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 25-01-2011 |
| 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 | NL2588 |
| NTR-old | NTR2713 |
| Ander register | WC : 2010-022 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A