Effects of oral corticosteroids and DMSO on inflammatory signs and symptoms in Complex Regional Pain Syndrome type 1

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34845

Source
ToetsingOnline

Brief title
Corticosteroids vs DMSO on CRPS-1

Condition

- Other condition

Synonym
(post traumatic) dystrophy, CRPS

Health condition

pijn patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: BSIK

Intervention

Keyword: anti-inflammatory, Complex Regional Pain Syndrome, corticosteroids, DMSO

Outcome measures

Primary outcome

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.

Secondary outcome

- Safety of treatment with high dose corticosteroids and tolerance of both therapies is assessed by questionnaires and clinical evaluation.
- Reduction of inflammatory markers in urine and blood plasma compared to baseline and between groups.
- 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.
- 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.

- Improvement of health related quality of life as measured by the SF-36 to the

baseline and between the groups.

Study description

Background summary

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.

Study objective

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.

Intervention

Patients will be treated with DMSO cream 5 times a day, combined with placebo oral medication during a period of 26 days (tapering period included) or with prednisolone 60 mg/day during 2 weeks, where after tapered, combined with placebo cream 5 times a day.

Study burden and risks

The burden on the patients exists mainly of time it will consume. Patients are asked to visit the hospital 5 times for the measurements decribed 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with CRPS according to the clinical Budapest criteria

Exclusion criteria

Another (2nd) chronic pain syndrome, interfering with pain ratings; another syndrome interfering with functional tests; CRPS-1 in both hands or feet; known severe kidney insufficiency, severe liver disease; active infection; established severe osteoporosis; gastric ulcera, hypersensitivity or allergy to prednisolone, use of anti-coagulantia, medication, myasthenia gravis, previous use of DMSO for a period longer than 1 month.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-11-2010
Enrollment:	152
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dimethyl Sulfoxide cream (DMSO cream)
Generic name:	Dimethyl Sulfoxide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	prednisolone
Generic name:	prednisolone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-019891-54-NL
CCMO	NL31129.029.10