Oral steroids for the treatment of inflammatory Complex Regional Pain Syndrome type-1

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Primary Objective: Assessment of a group difference in clinically important improvement in functional outcome of at least 10 points as measured by the DASH questionnaireSecondary Objective(s): 1. To determine if there is a group difference in...

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

Summary

ID

NL-OMON43832

Source
ToetsingOnline

Brief title
OSTIN

Condition

- Other condition

Synonym
reflex sympathetic dystrophy

Health condition

neurogeen inflammatoir pijn syndroom

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: stichting esperance

Intervention

Keyword: CRPS-1, steroids, treatment

Outcome measures

Primary outcome

Assessment of a group difference in clinically important improvement in

functional outcome of at least 10 points as measured by the DASH questionnaire

Secondary outcome

1. To determine if there is a group difference in improvement in global

perceive effect of therapy as measured on a 7 point scale

2. To determine if there is a group difference in improvement in pain intensity

scores as measured by a pain diary three times daily during the week before

each study visit.

3. To determine if there is a group difference in improvement in edema as

measured by a measurement tape

4. To determine if there is a group difference in improvement in discoloration

as measured on a 3 point scale

5. To determine if there is a group difference in cortisol levels of responders

to treatment versus non responders.

6. To determine if there is a group difference in improvement in

skin temperature difference as measured on a 5 point scale

7. To determine if there is a group difference in improvement of

QOL (quality of life)

Study description

Background summary

The treatment of Complex Regional Pain Syndrome type 1 (CRPS-1) still remains difficult, there is no clear proven medical or interventional therapy that improves clinical outcome of this syndrome. A lack of understanding the underlying pathophysiology of CRPS contributes to the difficulty in developing definitive treatments. (Cossins, 2013)
It is obvious that CRPS-1 needs to be treated as early as possible to avoid the syndrome from becoming chronic. (v Eijs, 2012) About 30% of CRPS-1 patients may become chronic despite treatment. (Duman, 2006, Schwartzmann 2009, de Mos 2009) Chronic CRPS-1 is debilitating and may lead to a completely non functional and extremely painful limb which eventually may even result in amputation. (Bodde, 2011) Pathophysiological studies have shown that inflammation is a key factor in the etiology of CRPS-1 (Parkitney, 2013) Several studies on anti-inflammatory mediators have shown different success rates. (Dirckx, 2012) It is suggested that anti-inflammatory agents such as prednisolon, biphosphonates and topical application of dimethyl sulfoxide may be beneficial in the acute stage of CRPS-1. (Birklein, 2015) The possible favourite response to prednisone 30 mg thrice daily was first demonstrated in an non blinded randomized trial in 23 patients. (Christensen, 1982) Other studies with oral steroids suggest the possible benefits of its use in post stroke CRPS-1. (Braus, 1994, Kalita, 2006) A recent retrospective evaluation of prednisolone 30 mg / day, tapered by 5 mg/day until discontinuation after 3 weeks in 45 patients with CRPS-1 showed significant improvement in clinical symptoms. (Atalay, 2014) So oral steroids may be useful in Crps-1 but good quality evidence is still lacking. Oral steroids may improve functional outcome of early CRPS-1 by diminishing swelling and pain and facilitating physical therapy. It may prevent patients with an affected extremity from becoming permanently disabled. Although almost all studies have been performed with pain reduction as the primary outcome parameter, we feel that early improvement in functional outcome is more important for the long term outcome when treating this syndrome. Therefore we aim for functional restoration as the primary outcome measurement and pain as the secondary outcome measurement

Study objective

Primary Objective:

Assessment of a group difference in clinically important improvement in functional outcome of at least 10 points as measured by the DASH questionnaire

Secondary Objective(s):

1. To determine if there is a group difference in improvement in global perceive effect of therapy as measured on a 7 point scale
2. To determine if there is a group difference in improvement in pain intensity scores as measured by pain diary three times daily during the week before each study visit.
3. To determine if there is a group difference in improvement in edema as measured by a measurement tape
4. To determine if there is a group difference in improvement in discoloration as measured on a 3 point scale
5. To determine if there is a group difference in improvement in skin temperature difference as measured on a 5 point scale
6. To determine if there is a group difference in cortisol levels of responders to treatment versus non responders.

Study design

double blinded randomized controlled trial in 2 x 26 subjects. Expected inclusion period will last two years. Follow up at 1, 3, 6, 9 and 12 months after randomization. The total duration is estimated at 3 years. Primary endpoint is at 3 months after randomization, secondary endpoint at 12 months follow up.

Intervention

prednisolon tablets
first week: 3 x 10 mg dd
sec week: 3 x 5 mg dd
third week 1 x 5 mg dd

Study burden and risks

the filling in of a questionnair of 3-5 minutes duration (DASH)
Pain diary 3x/day during 1 week before a study visit: 6 visits in total time 0, 1, 3, 6, 9 en 12 maanden.
Physical examination of the involved limb, edema measurement

Contacts

Public
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60

Tilburg 5022GC
NL
Scientific
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. CRPS-1 (clinical Budapest criteria) in one arm only.
2. Inflammatory type: painful upper extremity, temperature difference, swelling, red discoloration, limited hand function.
3. Occurring after trauma or upper extremity surgery
4. Acute stadium of less than 12 months duration
5. Diminished functioning of the upper extremity as established by a DASH score of 10 or more (Hudak, 1996)
6. Average pain score of 3 or more on a one week pain diary, three times daily
7. No indication for surgical therapy or no future surgery planned
8. Age 18-80

Exclusion criteria

not able to comply with follow up visits
<18 or > 80 years of age
more than one extremity involved
body temperature of > 38 degrees Celsius
Elevated white blood cell count (> 10-E9/liter)

Elevated BSE and CRP
Associated Infectious disease
Pregnancy
Coagulation disorders, use of anticoagulants
untreated peptic ulcer, hypertension, untreated diabetes, untreated cardiac failure

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2015
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Prednisolon
Generic name:	Prednisolon
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	03-03-2016

Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-07-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
Other	22812
EudraCT	EUCTR2015-004154-18-NL
CCMO	NL53776.028.15