Oral steroids for the treatment of inflammatory CRPS-1

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27326

Source
Nationaal Trial Register

Brief title
OSTIN

Health condition

complex regional pain syndrome type-1

Sponsors and support

Primary sponsor: NA
investigator initiated research
Source(s) of monetary or material Support: Stichting Esperance

Intervention

Outcome measures

Primary outcome

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 outcome

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 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. A responder is a subject who has at least 10 points improvement in the DASH questionnaire

Study description

Study objective

the active treatment group has an improvement of at least 10 points of DASH functional outcome more than the placebo group.

Study design

Follow up will be at 1, 3, 6, 9 and 12 months after randomization and start of treatment

Intervention

prednisolon versus placebo

Contacts

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Eligibility criteria

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

1. Not able to comply with follow up visits

2. < 18 or > 80 years of age

3. More than one extremity involved

4. Body temperature of ¡Ý 38 degrees Celsius

5. Elevated white blood cell count (> 10-E9 / liter)

6. Elevated BSE or CRP

7. Associated Infectious disease

8. Peptic ulcer

9. Pregnancy

10. Coagulation disorders, use of anticoagulants

11. Untreated hypertension

12. Untreated diabetes

13. Untreated cardiac failure

14. Current steroid use

15. Liver or kidney failure

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-10-2015
Enrollment:	52
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL5261
NTR-old	NTR5377
CCMO	NL-OSTIN 2015-003

Study results