Mannitol to prevent an exacerbation of Complex Regional Pain Syndrome (CRPS) after hand surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25885

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Complex Regional Pain Syndrome

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The Impairment Level Sum Score (ISS) after 3 months, which is a composite score, accounting for pain, edema, temperature and range of motion.

Secondary outcome

1. Disability of Arm, Shoulder and Hand, Dutch Language Version (DASH-DLV) score;

2. Individual components of ISS;

3. Perioperative VAS-pain scores;

4. Number of medication changes;

5. Side effects.

Study description

Background summary

Introduction: Complex Regional Pain Syndrome (CRPS) is a syndrome that may lead to chronic pain and disability of the extremities. Surgery or trauma cause about 75% of cases. A recurrence or exacerbation of complaints may be triggered by surgery, with recurrence rates being reported between 29 and 72%.

Up till now, no prophylaxis against the recurrence of CRPS after surgery has been studied in a randomized, controlled way. Several interventions have been reported to be effective in retrospective analyses, however.

Mannitol has been proposed for the prevention of a relapse of CRPS after surgery due to its oxygen-radical scavenging properties. In the Netherlands, it is therefore often used perioperatively, though evidence for its effectiveness is lacking and side effects and additional costs are involved.
Aim: This study has been set up to establish whether perioperative administration of mannitol to patients with CRPS can prevent an exacerbation or recurrence of complaints.

Methods: Patients with CRPS in a single arm, undergoing plastic surgery on that arm, will be included. They will be randomized to mannitol or placebo treatment. The intervention consists of administering a 1000 ml/24h i.v. infusion of mannitol 10% or a placebo. To mask the diuretic effects of mannitol, a placebo tablet or 50 mg hydrochlorothiazide are administered, respectively.
Preoperatively and after 3 months follow-up, pain (VAS and McGill Pain Questionnaire, MPQ), volume, temperature and function (Range of Motion, ROM), are measured. These parameters are compounded to the Impairmant-level Sum Score (ISS). Patient’s assesment of (change of) pain and impairment are assessed by the Disability of Arm. Shoulder and Hand questionnaire – Dutch Language Version (DASH-DLV).

Outcomes: Primary outcome is the difference of change of ISS after 3 months between the intervention and treatment group. Secondary outcome parameters include DASH-DLV, perioperative VAS, numer of medication changes and number of side-effects.

Study objective

Does mannitol, administered intravenously during 48 hours, prevent a recurrence or an exacerbation of complex regional pain syndrome after surgery.

Study design

N/A

Intervention

The treatment group will receive mannitol 10%, 1l daily, via a continuous i.v. infusion, starting at the beginning of anesthesia. In addition, a placebo tablet hydrochlorothiazide is administerde twice daily, starting after surgery.

The placebo group will receive 1l NaCl 0.9%, also via continuous infusion starting at the beginning of anesthesia. In addition, patients will receive a tablet of 25 mg hydrochlorothiazide twice daily.
Treatment will continue for 48 hours postoperatively.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age at least 18 jaar;

2. History of CRPS, indicated by the presence of the following characteristics during the past 3 years (adapted CRPS I criteria according to Bruehl)

a. Continuing pain, disproportionate to any inciting event;

b. At least 1 symptom in of the following 4 categories:

b1. Sensory: hyperalgesia

b2. Vasomotor: temperature asymmetry or skin color changes or skin color asymmetry;

b3. Sudomotor/edema: edema or sweating changes or sweating asymmetry;

b4. Motor/trophic: diminished range of motion or motor dysfunction or trophic changes;

3. The presence of CRPS signs is not mandatory;

4. Surgery on the affected upper extremity (a.o. carpal-tunnelsyndrome, joint surgery on wrist and fingers).

Exclusion criteria

1. Allergy to mannitol;

2. Allergy to hydrochlorothiazide;

3. Clinically relevant renal impairment (creatinine >= 150% normal);

4. Hystory of cardiac failure (orthopnea, edema, exertional dyspnea, admissions for cardiac failure);

5. CRPS in both upper extremities;

6. Other pain syndromes affecting functional testing or pain scores;

7. Infection;

8. Pregnancy;

9. No informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	24-10-2005
Application type:	First submission

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	NL428
NTR-old	NTR468
Other	: N/A
ISRCTN	ISRCTN36315634

Study results

Summary results
N/A