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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25885

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Complex Regional Pain Syndrome

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The Impairment Level Sum Score (ISS) after 3 months, which is a composite score,

accounting for pain, edema, temperature and range of motion.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-10-2005
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	NL428
NTR-old	NTR468
Ander register	: N/A
ISRCTN	ISRCTN36315634

Resultaten

Samenvatting resultaten
N/A