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

Submission date	Recruitment status	Prospectively registered
27/01/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/01/2006	Completed	Results
Last Edited	Condition category	Individual participant data
08/09/2011	Musculoskeletal Diseases	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

#### Study objectives

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

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Received from local medical ethics committee

#### Study design

Randomised double blind active controlled parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Complex Regional Pain Syndrome (CRPS)

#### **Interventions**

The treatment group will receive mannitol 10%, 1l daily, via a continuous IV infusion, starting at the beginning of anesthesia. In addition, a placebo tablet hydrochlorothiazide is administered 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.

#### Intervention Type

Other

#### Phase

#### Primary outcome measure

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 measures

- 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

#### Overall study start date

01/01/2005

#### Completion date

01/01/2007

# **Eligibility**

#### Key inclusion criteria

- 1. Age at least 18 years
- 2. History of CRPS, indicated by the presence of the following characteristics during the past 3 years (adapted CRPS I criteria according to Bruehl):
- 2.1. Continuing pain, disproportionate to any inciting event
- 2.2. At least 1 symptom in one of the following 4 categories:
- 2.2.1. Sensory: hyperalgesia
- 2.2.2. Vasomotor: temperature asymmetry or skin color changes or skin color asymmetry
- 2.2.3. Sudomotor/edema: edema or sweating changes or sweating asymmetry
- 2.2.4. 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-tunnel syndrome, joint surgery on wrist and fingers)

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

## Target number of participants

50

#### Key exclusion criteria

- 1. Allergy to mannitol
- 2. Allergy to hydrochlorothiazide
- 3. Clinically relevant renal impairment (creatinine ≥150% normal)
- 4. History 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

#### Date of first enrolment

01/01/2005

#### Date of final enrolment

01/01/2007

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre University Medical Center

Utrecht Netherlands 3508 GA

# Sponsor information

#### Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

#### Sponsor details

Department of Anesthesiology P.O. Box 85500 Utrecht Netherlands 3508 GA

#### Sponsor type

Hospital/treatment centre

#### **ROR**

# Funder(s)

## Funder type

Hospital/treatment centre

#### Funder Name

University Medical Centre Utrecht (UMCU) (Netherlands) - Department of Anesthesiology

# **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration