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

Protocol serial number N/A

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

Study type(s)

Treatment

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

Not Specified

Primary outcome(s)

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

Key secondary outcome(s))

- 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

Completion date

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

https://ror.org/04pp8hn57

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration