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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Not Specified

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
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Sponsor type
Hospital/treatment centre

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

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