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Optimal perioperative analgesia in hand surgery

Submission date 26/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/12/2007	**Condition category** Surgery	[_] Individual participant data [_] 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
MCT-65009

Study information

Scientific Title

Study objectives
To compare two methods of analgesia, optimal perioperative analgesia OPA versus the usual analgesic treatment (UAT), in patients undergoing hand surgery, in terms of postoperative pain control, intensity and duration of the local inflammatory response, impact of pain on function and quality of life.

Trapeziectomy and carpal surgery, bone graph, wrist arthrodesis, distal radial arthrotomy, hand surgery/trauma of hand.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Comité d'éthique de la recherche, CHUM (Centre Hospitalier de l'Université de Montréal) on the 24th March 2003.

Study design
Randomised controlled 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
Hand surgery

Interventions
Experimental group: non-steroidal anti-inflammatory drug (NSAID) 1 hour before surgery, 1 daily after surgery.
Both groups (OPA and UAT) will receive the same treatment until their admission in the recovery room.

Trial details received: 12 September 2005

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Non-Steroidal Anti-Inflammatory Drugs (NSAID)

Primary outcome measure
Reducing pain intensity at rest and during active movements measured at 8 months.

Secondary outcome measures
1. The impact of pain on Quality of Life (QOL)
2. The impact of pain on activities
3. Inflammation
4. Function

Overall study start date
01/10/2003

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Patients, either sex, scheduled for trapeziectomy and carpal surgery:
1. Total and partial carpectomy
2. Bone graph
3. Wrist arthrodesis
4. Distal radial arthrotomy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Age under 18 years or older than 75 years
2. Pregnant
3. Allergic to morphine, local anesthetics
4. Suffering from other forms of chronic arthritis or other painful conditions treated chronically (every day) with analgesics (i.e. fibromyalagia)

5. Allergic or intolerant to NSAID (COX2 inhibitors)
6. Consuming anticoagulants which cannot be interrupted
7. Suffering from major cardiovascular problems
8. Suffering from cognitive or psychiatric problems, or drug abuse
9. Other recent hand surgery or axillary surgery with sequels
10. Living alone (no help at home)
11. Unable to understand French or English
12. Without phone access or likely to change address during follow-up

Date of first enrolment
01/10/2003

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Canada

Study participating centre
Hôpital Notre-Dame du CHUM
Montréal
Canada
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Sponsor information

Organisation
University Hospital of Montreal (CHUM) (Canada)

Sponsor details
Campus Hôtel-Dieu
3840 rue Saint-Urbain
Montréal
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Sponsor type
University/education

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-65009)

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