

Optimal perioperative analgesia in hand surgery

Submission date 26/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/12/2007	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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 graft, 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. fibromyalgia)

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

H2L 4M1

Sponsor information

Organisation

University Hospital of Montreal (CHUM) (Canada)

Sponsor details

Campus Hôtel-Dieu

3840 rue Saint-Urbain

Montréal

Canada

H2W 4M1

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