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A randomised controlled trial to compare the efficacy of two methods of local anaesthetic blocks in carpal tunnel decompression surgery

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
20/12/2013

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

N0227170359

Study information

Scientific Title

Study objectives
Is there any difference in the results of two techniques of local anaesthetic blocks in carpal tunnel surgery with regards to pain during infiltration of the anaesthetic, adequacy of the anaesthesia and duration of anaesthesia?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Carpal tunnel decompression

Interventions
20 patients with bilateral carpal tunnel syndromes would be recruited. Each patient would have one side operated in one setting. The other side would be operated in the next 4-6 weeks. Each patient would have a local anaesthetic block using one technique on one side and the other technique on the other side.
The first technique would involve infiltrating the operative site (skin and subcutaneous tissue) with 6ml of 2% lignocaine with a no. 23 needle.
The other technique would involve infiltration of 2.5ml of 2% lignocaine into the carpal tunnel followed by infiltration of the remaining 3.5ml into the skin and subcutaneous tissue at the site of the incision. The patient would be unaware of the technique used. The patient would be asked to score the pain felt during the administration of the local anaesthetic block using a verbal pain score. The time taken for complete anaesthesia over the site of the incision would be

noted. All the operations would be performed by one of the two surgeons in the trial using a standardised technique. It the patient experiences any pain during the operation, this would be recorded using a verbal pain score. Additional anaesthetic would be administered if needed. The duration of the operation and the tourniquet time would also be noted. These patients would be contacted by telephone the next day and asked about the need of analgesics postoperatively over a period of 24 hours and the pain scores at 0, 2 and 4 hours postoperatively.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Pain during the operation
2. Pain during the administration of the local anaesthetic block
3. Frequency of post operative analgesics needed

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2005

Completion date
05/07/2006

Eligibility

Key inclusion criteria
20 patients - calculated by Dr Arts - statistician at Durham University. Inclusion criteria: all patients with bilateral carpal tunnel syndrome who would need surgical decompression.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
1. Re-do carpal tunnel decompressions
2. Carpal tunnel decompressions requiring general anaesthetic
3. Peripheral neuropathy, vascular insufficiency

Date of first enrolment
01/06/2005

Date of final enrolment
05/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ward 34
Cleveland
United Kingdom
TS4 3BW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2006		Yes	No