

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	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/12/2013	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr S Patil

Contact details
Ward 34
The James Cook University Hospital
Marton Road
Cleveland
United Kingdom
TS4 3BW
+44 (0)1642 850 850
spatil@nhs.net

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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. If 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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Ward 34
Cleveland
United Kingdom
TS4 3BW

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

South Tees Hospitals NHS Trust

Results and Publications

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