

The role of the Flexor Sheath in Carpal Tunnel Decompression

Submission date

30/09/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

30/09/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

16/07/2009

Condition category

Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

University Hospital

Nottingham

United Kingdom

NG7 2UH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0192128859

Study information

Scientific Title

Study objectives

The purpose of the study will be to see whether preserving the flexor sheath during decompression of the carpal tunnel improves recovery.

We believe that by trying to keep an extra piece of tissue beneath the median nerve will provide a smooth gliding surface and aid recovery in time and function.

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)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Nervous System Diseases: Carpal tunnel syndrome (CTS)

Interventions

Randomised Controlled Trial to see whether preserving the flexor sheath during decompression of the carpal tunnel improves recovery.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Grip strengths
2. scar pain
3. Patient Evaluation Measure score

Secondary outcome measures

Not provided at time of registration

Overall study start date

30/07/2003

Completion date

31/12/2003

Eligibility

Key inclusion criteria

1. 100 affected patients (50 patients and 50 control patients)
2. male or female
3. aged 20-70

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

30/07/2003

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospital

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Queen's Medical Centre University Hospital NHS Trust (UK)

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?
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[Results article](#)

results

01/11/2006

Yes

No