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The role of the Flexor Sheath in Carpal Tunnel Decompression

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2009	Nervous System Diseases	

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
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?

Results article	results	01/11/2006	Yes	No