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A double blind prospective randomised controlled study comparing absorbable versus non-absorbable suture techniques in Carpal Tunnel Release.

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
02/12/2008

Condition category
Nervous System Diseases

[_] 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

Contact name
Mr Peter Molitor

Contact details
Northern Lincolnshire & Goole Hospitals NHS Trust
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0084144561

Study information

Scientific Title

Study objectives
Comparison of suturing techniques: the absorbable suturing technique of parpal tunnel release and the non-absorbable suturing technique, in terms of patient pain perception, scar tenderness and wound healing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind prospective randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Nervous System Diseases: Carpal tunnel syndrome (CTS)

Interventions
After patients have agreed to participate, they will be randomised into one or other of the treatment arms:
1. Technique A = Using a continuous subcuticular absorbable 3.0 polyglactin 910 (vicryl) suture
2. Technique B = Using interrupted non-absorbable 3.0 monofilament polypropylene (prolene) suture

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Residual postoperative pain using Visual Analogue Scale
2. Scar tenderness
3. Preoperative and postoperative symptoms using CTS Symptom Severity Score
4. Preoperative and postoperative functional status using CTS Functional Status Scale
5. Extent of wound healing

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2003

Completion date
30/04/2004

Eligibility

Key inclusion criteria
40 patients, aged between 18 to 75 years are invited to participate in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2003

Date of final enrolment
30/04/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
Scunthorpe
United Kingdom
DN15 7BH

Sponsor information

Organisation
Department of Health

Sponsor details
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
Northern Lincolnshire and Goole Hospitals NHS Trust (UK), NHS R&D Support Funding

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	01/02/2005		Yes	No