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Carpal Tunnel Syndrome Diagnosis and Treatment Trial

Submission date	Recruitment status	[_] Prospectively registered
09/09/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/10/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2009	Musculoskeletal Diseases	

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
NCT00032227

Secondary identifying numbers
P60 AR48093

Study information

Scientific Title

Study objectives
Conservative treatment remains the standard of care for treating mild to moderate carpal tunnel syndrome despite a small number of well-controlled studies and limited objective evidence to support current treatment options. There is an increasing interest in the usefulness that wrist magnetic resonance imaging could play in predicting who will benefit for various treatments. We have designed a randomised controlled trial which will assess the effectiveness of surgery for patients with mild to moderate carpal tunnel syndrome. An important secondary goal is to study the ability of MRI to predict patient outcomes.

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 syndrome

Interventions
Surgical release versus Conservative treatment including ultrasound.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The SF-36 Health Survey version 2 (QualityMetics Inc., Ware) has been used to assess general health status in samples of patients with a variety of diseases, including CTS. It consists of eight domains (general health, physical functioning, role limitations due to physical problems, role limitations due to emotional problems, bodily pain, social function, mental health, and vitality) scored on a scale of 0 (worst health) to 100 (ideal health). We will compare the two groups on each scale as well as the physical and mental summary scores. The generic nature of the instrument allows comparison across health conditions.

Study participants also complete the Symptom Check List SCL-90 12-item Somatization and 13-item Depression scales. Participants respond to each question using a 5-point scale ranging from "not at all" to "extremely". Higher scores indicate greater somatisation/depressive symptom severity.

Secondary outcome measures
The 13-item Pain Catastrophizing Scale is used as both a predictor and a secondary outcome. A substantial volume of research had consistently found substantial associations between pain-related catastrophising and pain-related disability. We are interested in learning whether pain-related catastrophising is a risk factor for poor outcomes in patients with CTS.

Overall study start date
01/08/2002

Completion date
30/04/2008

Eligibility

Key inclusion criteria
1. Patients with mild to moderate carpal tunnel syndrome confirmed by electrodiagnostic study (EDS) testing
2. Must have symptoms in at least 2 digits
3. Must have completed at least a 2 week trial of standard therapy without improvement as documented by at least one of the following:
a. Improvement less than 0.75 in the Carpal Tunnel Syndrome Assessment Questionnaire (CTSAQ) functional scale
b. Unable to achieve "satisfactory" level of work
c. Patient defined symptoms as being "same" or "worse" over the last two weeks
4. EDS CRITERIA:
i. Median motor latency (wrist) ≥4.4 ms
ii. Sensory: Medial-radial (10 cm thumb to wrist) difference >0.5 ms
iii. Sensory: Midpalm median-ulnar (8 cm) difference >0.3 ms
iv. Sensory: Median-ulnar (14 cm digit IV to wrist) difference >0.4 ms
v. Sensory: Combined Sensory Index ≥1.0 ms
5. Or normal EDS with night pain that wakes patient AND Positive Flick Test
6. Other inclusion criteria:
Classic, probable or possible hand diagram
7. Willing to schedule surgery within one week of randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
Patients with evidence of severe CTS on EDS, EMG, or clinical findings are excluded from the study. Severe CTS is defined as a median motor amplitude of </= 3.8 mV, EMG evidence of denervation, or thenar atrophy.

Date of first enrolment
01/08/2002

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
United States of America

Study participating centre
Multidisciplinary Clinical Research Center
Seattle, WA
United States of America
98104

Sponsor information

Organisation
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (USA)

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/006zn3t30

Funder(s)

Funder type
Government

Funder Name
National Institute of Arthritis and Musculoskeletal and Skin Diseases - NIH P60 AR48093 (USA)

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?
Protocol article	protocol	18/01/2005		Yes	No
Results article	results	26/09/2009		Yes	No