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Surgical decompression versus local steroid injection in carpal tunnel syndrome

Submission date
22/12/2011

Recruitment status
No longer recruiting

Registration date
02/02/2012

Overall study status
Completed

Last Edited
05/10/2012

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Carpal tunnel syndrome (CTS) is a condition due to the median nerve in the wrist being trapped. This irritates the median nerve and produces a wide variety of symptoms, such as pain or numbness in the hand.
To date, there are only two treatments that are known to work:
1. Local corticosteroid injection in the wrist
2. Surgical decompression of the nerve
The objective of this study is to compare the two forms of treatment.

Who can participate?
You can participate in the study if you are 18 year old or older and your doctor thinks you have CTS.

What does the study involve?
A group of wrists are treated with surgical decompression and another group of wrists are treated with one or two local corticosteroid injections. The results of the treatment will be followed for two years.

What are the possible benefits and risks of participating?
Participants are treated with one out of two well established treatments so there will not be risks. Benefits of participating include being treated for the condition. Expected side effects are local discomfort for several days after the injection or the surgical decompression.

Where is the study run from?
The study is carried out in Centro de Salud Gandhi, Madrid and in Hospital Universitario Ramón y Cajal, Madrid, Spain.

When is study starting and how long is it expected to run for?
The study started on 01 October 1998 and finished on 31 May 31 2001.

Who is funding the study?
Spanish National Health System

Who is the main contact?
Prof José Luis Andreu
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
STC98

Study information

Scientific Title
Surgical decompression versus local steroid injection in carpal tunnel syndrome: a prospective randomised trial

Study objectives
Steroid injection is as effective and safe as surgical decompression in carpal tunnel syndrome (CTS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital Ramon y Cajal Ethics Committee, 14 September 1998 ref: 67/98

Study design

Prospective randomized open comparative clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Carpal tunnel syndrome

Interventions
Local steroid injection versus surgical decompression for new-onset CTS.

All surgical procedures are performed on an outpatient basis using a limited palmar incision technique. Local steroid injections are performed using a standard technique: the steroid is instilled beneath the transverse carpal ligament from the ulnar side of the wrist. A 22-gauge needle is positioned 1 cm proximal to the distal wrist-flexion crease and medial to the palmaris longus tendon. The needle is passed at a 45 degree angle distally and advanced 12 cm in depth, and then paramethasone acetonide, 20mg in 1ml, is instilled.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Percentage of wrists reaching at least a 20% reduction in the VAS score for nocturnal paresthesias at 3 months of follow up.

Secondary outcome measures
Percentages of wrists with a 20% reduction in the VAS score for nocturnal paresthesias at 6 and 12 months, a 20% response for pain and functional impairment, as well as a 50% and a 70% response in nocturnal paresthesias, pain, and functional impairment.

Overall study start date
01/10/1998

Completion date
31/05/2001

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Symptoms of CTS of at least 3 months duration
3. Referred by their primary care physicians to a CTS unit specifically created for this study
4. A presumptive diagnosis of CTS, and had been unresponsive to a course of at least 2 weeks of non-steroidal anti-inflammatory drugs (NSAIDs) and splinting.
5. CTS confirmed by electrodiagnostic testing according to Kimura´s criteria.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients with wrists with thenar atrophy
2. Previous carpal tunnel release surgery, or local injection for CTS
3. Patients who are pregnant
4. Patients which have diabetes mellitus
5. Patients which have hypothyroidism
6. Patients which have inflammatory arthropathy
7. Patients which have polyneuropathy

Date of first enrolment
01/10/1998

Date of final enrolment
31/05/2001

Locations

Countries of recruitment
Spain

Study participating centre

Servicio de Reumatología
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Sponsor information

Organisation
University Hospital Puerta de Hierro Majadahonda (Spain)

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Sponsor type
University/education

ROR
https://ror.org/01e57nb43

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Spanish National Health System (Spain)

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	01/08/2012		Yes	No