

Surgical decompression versus local steroid injection in carpal tunnel syndrome

Submission date 22/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/02/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/10/2012	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Majadahonda

Spain

28222

Sponsor information

Organisation

University Hospital Puerta de Hierro Majadahonda (Spain)

ROR

<https://ror.org/01e57nb43>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Spanish National Health System (Spain)

Results and Publications

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