

# The clinical and cost effectiveness of of a steroid injection versus a night splint for Carpal Tunnel Syndrome

<b>Submission date</b> 01/05/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Carpal Tunnel Syndrome (CTS) is a common condition in which a nerve (known as the median nerve) is squeezed where it passes through the wrist. It can cause pain or aching, tingling or numbness in the affected hand. It may disturb sleep, or affect ability to do day to day things. There have been several studies into the best treatment of patients with severe symptoms of CTS who are referred to a hospital for treatment. However, little is known about the best treatments for patients with mild to moderate symptoms who visit their GP but do not require hospital treatment. This study aims to find out whether a single steroid injection is effective in treating CTS symptoms when compared with a night splint in people suffering with mild to moderate carpal tunnel syndrome.

### Who can participate?

Patients aged 18 and over who have been diagnosed with mild to moderate CTS which has been present for at least 6 weeks

### What does the study involve?

Each participant is randomly allocated to receive either a single steroid injection or a splint, and is asked to complete up to five questionnaires over 2 years. The steroid is a drug called DepoMedrone and is already widely used to treat CTS. The splint is made of elastic and has an aluminium bar which sits on the palm of the hand. In this study, the splint will be worn at night for 6 weeks. We study the effects of these two treatments over 6 weeks and at 6 months. We also look at whether these 6 weeks of treatment are effective 1 year and 2 years later.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

The study will take place in up to 50 GP practices and hospital clinics across the UK

When is the study starting and how long is it expected to run for?  
April 2014 to September 2017

Who is funding the study?  
Arthritis Research UK

Who is the main contact?  
Jacqueline Gray  
j.gray@keele.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Jacqueline Gray

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT02038452

**Clinical Trials Information System (CTIS)**  
2013-001435-48

**Protocol serial number**  
16390

## Study information

**Scientific Title**  
The clinical and cost effectiveness of of a steroid injection versus a night splint for Carpal Tunnel Syndrome: a pragmatic randomised trial in primary care

**Acronym**  
INjection versus SplinTing in Carpal Tunnel Syndrome (INSTinCTS)

**Study objectives**

The study aims to find out whether a single steroid injection is effective in treating CTS symptoms when compared with a night splint in people suffering with mild to moderate carpal tunnel syndrome.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

13/NW/0280; First MREC approval date 07/05/2013

### **Primary study design**

Interventional

### **Study design**

Randomised; Interventional; Design type: Treatment

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Topic: Primary Care, Musculoskeletal disorders; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: All Diseases, Musculoskeletal Pain Disorders

### **Interventions**

Each participant will receive either a single steroid injection or a splint. The steroid is a drug called DepoMedrone 20mg. This drug is already widely used to treat CTS. In this study, one injection will be given. The splint is made of elastic and has an aluminium bar which sits on the palm of the hand. In this study, the splint will be worn at night for 6 weeks. Each participant will be asked to complete up to 5 questionnaires over 2 years. We will study the effects of these 2 treatments over 6 weeks and at 6 months. Subject to further funding, the Study will also look at whether these 6 weeks of treatment are effective 1 year and 2 years later.

### **Intervention Type**

Drug

### **Phase**

Phase IV

### **Drug/device/biological/vaccine name(s)**

Depo-medrone

### **Primary outcome(s)**

Symptom severity and limitations in hand function as assessed by the Boston CTS questionnaire; Timepoint(s): 6 weeks, 6 months, 12 months and 24 months post-randomisation.

### **Key secondary outcome(s)**

Not provided at time of registration

### **Completion date**

31/12/2018

# Eligibility

## Key inclusion criteria

1. Male or female aged 18 years or over
2. A clinical diagnosis of unilateral or bilateral CTS as made by a GP or trained clinician according to the diagnostic criteria
3. Mild (e.g. intermittent paraesthesia) or moderate (e.g. constant paraesthesia, reversible numbness and / or pain) severity CTS of idiopathic nature
4. Symptom duration of episode of at least 6 weeks
5. Written informed consent provided by the patient, prior to any trial specific procedures

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 Years

## Sex

All

## Key exclusion criteria

1. Steroid injection or night splints for CTS in the affected wrist within preceding 6 months
2. Any previous surgery on the affected wrist
3. Severe CTS exhibiting constant numbness or pain, constant sensory loss, severe thenar muscle atrophy or symptom severity which requires the patient to be referred for a surgical opinion
4. Clinical suspicion of local or systemic sepsis or infection
5. Current or previous infection of the affected wrist
6. Trauma to the affected hand requiring surgery or immobilisation in the previous 12 months
7. Unable to tolerate the study interventions
8. Unable to understand and complete self report questionnaires written in English
9. Intercurrent illness including, but not limited to: poorly controlled thyroid disease, poorly controlled diabetes mellitus, vibration-induced neuropathy, inflammatory joint disease, suspected complex neurological conditions, any other severe medical illness which in the opinion of the local Principal Investigator (or other authorised clinical delegate) precludes trial participation
10. Pregnant or lactating females
11. Receiving anticoagulants
12. Any history of hypersensitivity to DepoMedrone or any of its excipients (refer to the Summary of Product Characteristics (SPC))
13. Allergy to any of the splint materials (refer to manufacturers specification)
14. Known abuse of drugs or alcohol
15. Involved in ongoing litigation cases for their condition

## Date of first enrolment

17/04/2014

**Date of final enrolment**

01/09/2017

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Keele University**

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

## Sponsor information

**Organisation**

University of Keele (UK)

**ROR**

<https://ror.org/00340yn33>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Arthritis Research UK (UK)

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Linda Chesterton, l.s.chesterton@keele.ac.uk

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	20/10/2018		Yes	No
<a href="#">Protocol article</a>	protocol	06/10/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No