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

Submission date
01/05/2014

Recruitment status
No longer recruiting

Registration date
01/05/2014

Overall study status
Completed

Last Edited
26/03/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-001435-48

IRAS number

ClinicalTrials.gov number
NCT02038452

Secondary identifying numbers
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

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
18/12/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 240; UK Sample Size: 240

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
England

United Kingdom

Study participating centre
Keele University
Newcastle-Under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
University of Keele (UK)

Sponsor details
Keele
Newcastle
England
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Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2018

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?
Protocol article	protocol	06/10/2016		Yes	No
Results article	results	20/10/2018		Yes	No

HRA research summary	28/06/2023	No	No