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Steroid injection versus surgical decompression for carpal tunnel syndrome

Submission date
20/07/2016

Recruitment status
No longer recruiting

Registration date
20/07/2016

Overall study status
Completed

Last Edited
22/04/2021

Condition category
Nervous System Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary

Background and study aims
Carpal Tunnel Syndrome (CTS) the most common nerve compression disorder. It is happens because one of the central nerves in the wrist (median nerve) is compressed, leading to tingling, numbness and pain in the hand, particularly at night. Patients usually report that the night symptoms are the most troublesome as the pain can be unrelenting and sleep can be disturbed every night. Mild cases are treated with wrist splints and steroid injection. Severe nerve compression may require an operation to decompress the nerve however. Both injection and surgery are used for moderate cases but there is no clear evidence as to which is best. Some clinicians argue that all patients should receive an injection first, reserving the more expensive and invasive surgery for when this fails. Others offer early surgery, arguing that around 80% of injections fail within one year and that surgery is effective and safe. As a result, there is variation in practice across the country in the management of moderate CTS and there are no national guidelines. Commissioners' policies for funding surgery also vary greatly. A large study is going to be developed in order to compare early surgery with injection and surgery later if required, looking at the effectiveness, safety and cost of both approaches. In order to assess whether a study of this nature is possible it is necessary to perform a smaller version of the study (pilot study) which will assess the willingness of patients to participate and identify any difficulties that the larger study may encounter.

Who can participate?
Adults with CTS which is disturbing their sleep or limiting their ability to use their hand who have found wearing night splints to be ineffective.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a steroid injection into the carpal tunnel. The injection is given by a qualified and experienced health care professional and can be done at the same time as the patient joins the study to save any further appointments or delay. Often patients do not require any further treatment after an injection however if the symptoms come back, they can contact the local research team at any stage to discuss whether they should have surgery. Those in the second group undergo a small operation to relieve pressure on the nerve (decompression surgery). The surgery takes around 10 minutes and is usually done under local anaesthetic (injection to numb the hand). Participants

in both groups complete a number of questionnaires at the start of the study and then after 3, 6 and 12 months to find out if their symptoms have improved. After 12 months, the number of participants who were eligible, agreed to take part, and completed all follow up is recorded to find out whether conducting a larger trial would be possible.

What are the possible benefits and risks of participating?
There are no guaranteed benefits to patients who take part in this study although they may find the treatment approach they are allocated to receive improves their symptoms. There are no anticipated risks to participating in this study. Whichever type of treatment patients are allocated to, their care will be coordinated by a competent and trained health care professional. Both treatments have a very low risk of complications, although clearly surgery does carry more risk than an injection. These will be explained to the patient as part of routine care. Steps are always taken to ensure that these risks are minimised.

Where is the study run from?
Gloucester Royal Hospital (lead centre), Derriford Hospital and Kent & Canterbury Hospital (UK)

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

Who is funding the study?
The British Society for Surgery of the Hand (UK)

Who is the main contact?
Mrs Cushla Cooper
cushla.cooper@ndorms.ox.ac.uk

Study website
https://www.situ.ox.ac.uk/surgical-trials/indicate

Contact information

Type(s)
Public

Contact name
Mrs Cushla Cooper

Contact details
Surgical Intervention Trials Unit
Nuffield Department of Surgical Sciences
Botnar Research Centre
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
Oxford
United Kingdom
OX3 7HE
+44 (0)1865 737643
cushla.cooper@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19860

Study information

Scientific Title
Injection or Decompression in Carpal Tunnel Syndrome - Pilot Study (INDICATE--P)

Acronym
INDICATE--P

Study hypothesis
The aim of this study is to evaluate the feasibility of a study assessing whether a steroid injection given initially is better than having surgery for patients with moderate carpal tunnel syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester Central Research Ethics Committee, 23/07/2015, ref: 15/EM/0298

Study design
Randomised; Interventional; Design type: Treatment, Drug, Surgery

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 to request a patient information sheet

Condition

Specialty: Musculoskeletal disorders, Primary sub-specialty: Metabolic bone disease

Interventions

Participants are randomised to one of two groups using a web-based randomisation system will be provided by the Oxford Clinical Trials Research Unit (OCTRU). A computer will generate the random sequence which will be simple block randomisation, stratified by centre to ensure a similar number of patients are allocated to each treatment arm at each site. Randomisation will take place once the patient has consented and all baseline data is collected.

Group 1: Participants receive a steroid injection at baseline. The technique of the injection will not be standardised but the practitioner should regularly give injections for CTS and use the technique with which they are most familiar. Further injections are not advisable whilst the patient is in the study, however, if more than one injection is given, this needs to be recorded as further treatment sort on the Complication Form.

Group 2: Participants receive decompression surgery. Participating surgeons will use the technique with which they are most familiar, whether it is open or endoscopic surgery, to avoid any learning curve effect. Peri-operative management including anaesthesia, analgesia and dressings should follow local protocols. Post-operative management including dressing changes, advice, exercises, scar management and follow up appointments should follow local protocols or the surgeon's preference. Specifically, it will not be necessary to have a follow-up appointment in secondary care, if that is not usual local practice.

All participants will be followed up clinically as per routine care at their hospital. For the study purposes they will be followed up with postal questionnaires at 1, 3, 6 and 12 months post randomisation in order to assess clinical differences between the two treatment options. This includes assessments on pain, function and quality of life

Intervention Type

Other

Primary outcome measure

Feasibility outcomes:
1. Eligibility rate is measured by recruitment numbers and screening logs during the recruitment phase
2. Recruitment rate is measured by the number of patients randomised to the trial and over what period of time
3. Adherance rate is measured by the number of withdrawals and losses to follow up over the 12 month period of the follow up process

Secondary outcome measures

1. Pain and function is measured using the Carpal Tunnel Assessment Questionnaire at baseline, 1, 3, 6 and 12 months
2. Pain is measured using the Palmar Pain scale at baseline, 1, 3, 6 and 12 months
3. Quality of Life is measured using the Global Outcome Scale and the EuroQol- 5D at baseline, 1, 3, 6 and 12 months
4. How satisfied patients are with their treatment outcome is measured using the Satisfaction Scale at 6, 12 months
5. Time off work/activities is measured by patient reports on resources use, complications and any further treatment sought at baseline, 1, 3, 6 and 12 months

Overall study start date
13/02/2014

Overall study end date
31/10/2017

Eligibility

Participant inclusion criteria
1. All three of the following must be present:
1.1. Intermittent paraesthesia in median nerve distribution
1.2. Nocturnal hypoaesthesia, dysaesthesia or paraesthesia (including on waking)
1.3. A positive provocation test (e.g. Tinel's, Phalen's, Durkin's pressure or hand elevation test)
2. Symptoms present for at least 3 months
3. Patients' symptoms must either:
3.1. Disturb their sleep
3.2. Limit their ability to perform work or activities of daily living
4. Patients must have failed a trial of night splints for at least 2 weeks
5. Age >18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Participant exclusion criteria
1. Severe CTS
1.1. Thenar muscle wasting or
1.2. Continuously reduced light touch sensation in median nerve distribution (compared to opposite unaffected side or unaffected finger)
2. Previous carpal tunnel surgery or steroid injection (either side)
3. CTS secondary to:
3.1. Wrist deformity, trauma or mass
3.2. Pregnancy
3.3. Hypothyroidism
3.4. Inflammatory arthropathy
4. Clinical or neurophysiological evidence of polyneuropathy or cervical radiculopathy
5. Other symptomatic disorder in the affected hand diagnosed in the last 6 months or requiring treatment.
6. Patients in whom the baseline questionnaire cannot be completed due to cognitive difficulties

Recruitment start date
24/11/2015

Recruitment end date
01/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gloucester Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Derriford Hospital
Plymouth Hospitals NHS Trust
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Kent & Canterbury Hospital
East Kent Hospitals University NHS Foundation Trust
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Sponsor information

Organisation

Gloucestershire Hospitals NHS Foundation Trust

Sponsor details
Gloucestershire Research Support Service
Leadon House
Gloucestershire Royal Hospital
Great Western Road
Gloucester
England
United Kingdom
GL1 3NN
+44 (0)300 422 5463
mark.walker@glos.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04mw34986

Funder(s)

Funder type
Charity

Funder Name
The British Society for Surgery of the Hand

Results and Publications

Publication and dissemination plan
Planned publication of the manuscript of the pilot study results once all follow up is completed, all data queries addressed, and the study team have reviewed the manuscript. Results will also be presented at national meetings of the British Society for Surgery of the Hand.

Intention to publish date
31/10/2018

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	24/04/2017		Yes	No
Other publications	letter	01/11/2020	22/04/2021	Yes	No
HRA research summary			28/06/2023	No	No