



Clinical trial results:

The clinical and cost effectiveness of a steroid injection versus a night splint for Carpal Tunnel Syndrome: a pragmatic randomised trial in primary care (INSTinCTS)

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2013-001435-48 |
| Trial protocol | GB |
| Global end of trial date | 26 February 2019 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 13 March 2020 |
| First version publication date | 13 March 2020 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 464/11 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|----------------|
| ISRCTN number | ISRCTN09392969 |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Keele University |
| Sponsor organisation address | Keele, Newcastle-under-Lyme, United Kingdom, ST5 5BG |
| Public contact | Clinical Studies Co-ordinator, Keele Primary Care Musculoskeletal Trials Unit (Keele CTU), 0044 01782 733909, e.skinner@keele.ac.uk |
| Scientific contact | Clinical Studies Co-ordinator, Keele Primary Care Musculoskeletal Trials Unit (Keele CTU), 0044 01782 733909, e.skinner@keele.ac.uk |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 20 February 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 26 February 2019 |
| Global end of trial reached? | Yes |
| Global end of trial date | 26 February 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to investigate whether a steroid injection is clinically effective in reducing symptoms and improving function in the short term (6 weeks) compared to a night splint in people consulting with mild to moderate carpal tunnel syndrome in primary care.

Protection of trial subjects:

The trial was performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland. Informed written consent was obtained from the participants prior to any trial-specific procedures taking place. The right of a participant to refuse participation without giving reasons was respected. The trial was submitted to and approved by a main NHS Research Ethics Committee (main REC) and the appropriate site approvals given for each participating centre prior to entering participants into the trial. Subsequent amendments were approved by the Health Research Authority (HRA), main REC and MHRA as required. All information collected during the course of the trial is kept strictly confidential. Keele CTU complied with all aspects of the applicable Data Protection Act.

Background therapy:

None

Evidence for comparator:

The most frequently reported and readily available treatments for carpal tunnel syndrome in primary care are splinting, anti-inflammatory medication and local corticosteroid injection. Systematic reviews (including Cochrane reviews) of nonsurgical conservative treatments have assessed local corticosteroid injections, oral steroid medication and splinting. Both night splinting and steroid injection lead to greater improvement in symptoms in the short-term over no treatment or placebo injection although evidence of longer benefit was unclear. Review authors concluded that many of the trials included in these reviews had a high risk of bias and more robust trials are needed to compare treatments and ascertain the duration of benefit. A direct comparison between the effects of steroid injection and splinting has been made in two small trials, neither of which were carried out in a primary care setting where most people with carpal tunnel syndrome are managed.

| | |
|---|---------------|
| Actual start date of recruitment | 17 April 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | United Kingdom: 234 |
| Worldwide total number of subjects | 234 |
| EEA total number of subjects | 234 |

Notes:

| Subjects enrolled per age group | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 174 |
| From 65 to 84 years | 56 |
| 85 years and over | 4 |

Subject disposition

Recruitment

Recruitment details:

Patients were recruited from 25 General Practices and community musculoskeletal clinics between 17/04/2014 and 31/12/2016

Pre-assignment

Screening details:

Patients with a positive CTS diagnosis were assessed for eligibility by the GP/clinician based on the inclusion/exclusion criteria. Patients who were interested in trial participation were then seen by appropriate member of the clinical team who explained the trial in full, and were asked to provide written informed consent.

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 234 |
| Number of subjects completed | 234 |

Period 1

| | |
|------------------------------|--|
| Period 1 title | Trial recruitment and follow up (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind |
| Roles blinded | Data analyst ^[1] |

Blinding implementation details:

Participants and clinicians were not blind to the allocation of treatment arm. The research nurses who conducted minimal data collection and statisticians were blind to allocation. Analysis of the primary outcome was conducted blind to arm allocation.

Arms

| | |
|------------------------------|-------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Steroid injection |

Arm description:

One injection of 20mg methylprednisolone acetate to infiltrate the carpal tunnel

| | |
|--|----------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Methylprednisolone acetate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Periarticular use |

Dosage and administration details:

One injection of 20mg methylprednisolone acetate (as 20mg of depo-medrone from 40mg/mL) via a disposable needle (23G or 25G) and syringe which was inserted at the wrist between the proximal and distal wrist crease to infiltrate the carpal tunnel.

| | |
|------------------|--------|
| Arm title | Splint |
|------------------|--------|

Arm description:

Participants received a beta wrist brace which immobilised the wrist in a neutral or slightly extended position intended to reduce pressure within the carpal tunnel, to wear at night for 6 weeks.

| | |
|---|--------------|
| Arm type | Wrist splint |
| No investigational medicinal product assigned in this arm | |

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Analysis was performed blind to treatment allocation. Data collection was self-reported but a blind assessor collected data from questionnaire non-responders.

| Number of subjects in period 1 | Steroid injection | Splint |
|---------------------------------------|-------------------|--------|
| Started | 116 | 118 |
| Baseline | 113 | 117 |
| 6 weeks follow-up | 108 | 109 |
| 6 months follow-up | 96 | 97 |
| 12 months follow-up | 87 | 88 |
| 24 months follow-up | 78 | 81 |
| Completed | 78 | 81 |
| Not completed | 38 | 37 |
| Consent withdrawn by subject | 7 | 9 |
| Lost to follow-up | 31 | 28 |

Baseline characteristics

Reporting groups

| | |
|---|-------------------|
| Reporting group title | Steroid injection |
| Reporting group description: | |
| One injection of 20mg methylprednisolone acetate to infiltrate the carpal tunnel | |
| Reporting group title | Splint |
| Reporting group description: | |
| Participants received a beta wrist brace which immobilised the wrist in a neutral or slightly extended position intended to reduce pressure within the carpal tunnel, to wear at night for 6 weeks. | |

| Reporting group values | Steroid injection | Splint | Total |
|--|-------------------|--------|-------|
| Number of subjects | 116 | 118 | 234 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 85 | 89 | 174 |
| From 65-84 years | 28 | 28 | 56 |
| 85 years and over | 3 | 1 | 4 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 52.6 | 52.2 | - |
| standard deviation | ± 17.0 | ± 14.9 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 73 | 81 | 154 |
| Male | 43 | 37 | 80 |
| First time diagnosed with CTS | | | |
| CTS: Carpal Tunnel Syndrome | | | |
| Units: Subjects | | | |
| Yes | 97 | 102 | 199 |
| No | 16 | 15 | 31 |
| Missing | 3 | 1 | 4 |
| Number of times previously had CTS | | | |
| CTS: Carpal Tunnel Syndrome | | | |
| Units: Subjects | | | |
| N/A | 97 | 102 | 199 |
| One | 11 | 8 | 19 |
| Two | 1 | 1 | 2 |
| Three | 0 | 0 | 0 |
| More than three | 3 | 4 | 7 |
| Missing | 4 | 3 | 7 |
| Hand or wrist previously affected by | | | |

| | | | |
|---|-----|-----|-----|
| CTS | | | |
| CTS: Carpal Tunnel Syndrome | | | |
| Units: Subjects | | | |
| N/A | 97 | 102 | 199 |
| Right | 6 | 3 | 9 |
| Left | 1 | 2 | 3 |
| Both | 8 | 9 | 17 |
| Missing | 4 | 2 | 6 |
| Steroid injection into a joint other than wrist if previously had CTS | | | |
| CTS: Carpal Tunnel Syndrome | | | |
| Units: Subjects | | | |
| N/A | 97 | 102 | 199 |
| Yes | 9 | 9 | 18 |
| No | 7 | 6 | 13 |
| Missing | 3 | 1 | 4 |
| Usefulness of injection into other joint if previously had CTS | | | |
| CTS: Carpal Tunnel Syndrome | | | |
| Units: Subjects | | | |
| N/A | 104 | 108 | 212 |
| Of great help | 7 | 7 | 14 |
| Of some help | 1 | 1 | 2 |
| Of little help | 0 | 0 | 0 |
| Of no help | 1 | 1 | 2 |
| Missing | 3 | 1 | 4 |
| Which problematic hand or wrist | | | |
| Units: Subjects | | | |
| Right | 36 | 37 | 73 |
| Left | 19 | 20 | 39 |
| Both | 57 | 59 | 116 |
| Missing | 4 | 2 | 6 |
| If both hands problematic, which hand was worse | | | |
| Units: Subjects | | | |
| N/A | 55 | 57 | 112 |
| Right | 25 | 24 | 49 |
| Left | 13 | 19 | 32 |
| No difference | 7 | 3 | 10 |
| Missing | 16 | 15 | 31 |
| Dominant hand | | | |
| Units: Subjects | | | |
| Right | 99 | 99 | 198 |
| Left | 12 | 16 | 28 |
| Missing | 5 | 3 | 8 |
| Duration of hand or wrist problems | | | |
| Units: Subjects | | | |
| <3 months | 19 | 17 | 36 |
| 3-6 months | 37 | 33 | 70 |
| 6 months-1 year | 22 | 27 | 49 |
| >1 year | 34 | 39 | 73 |
| Missing | 4 | 2 | 6 |

| | | | |
|--|----|----|-----|
| How did hand or wrist problems start Units: Subjects | | | |
| Suddenly | 33 | 17 | 50 |
| Gradually | 79 | 99 | 178 |
| Missing | 4 | 2 | 6 |
| Particular position causes hand or wrist problems Units: Subjects | | | |
| Yes | 50 | 62 | 112 |
| No | 62 | 54 | 116 |
| Missing | 4 | 2 | 6 |
| Currently taking pain relief Units: Subjects | | | |
| Yes | 36 | 34 | 70 |
| No | 77 | 83 | 160 |
| Missing | 3 | 1 | 4 |
| Number of times a day taking pain relief Units: Subjects | | | |
| N/A | 77 | 83 | 160 |
| One | 7 | 8 | 15 |
| Two | 13 | 5 | 18 |
| Three | 5 | 5 | 10 |
| Four | 3 | 5 | 8 |
| Five | 0 | 1 | 1 |
| Missing | 11 | 11 | 22 |
| Number of days per week taking pain relief Units: Subjects | | | |
| N/A | 77 | 83 | 160 |
| One | 0 | 0 | 0 |
| Two | 1 | 4 | 5 |
| Three | 3 | 0 | 3 |
| Four | 1 | 0 | 1 |
| Five | 2 | 2 | 4 |
| Six | 0 | 0 | 0 |
| Seven | 14 | 7 | 21 |
| Missing | 18 | 22 | 40 |
| Number of weeks in a month taking pain relief Units: Subjects | | | |
| N/A | 77 | 83 | 160 |
| One | 1 | 0 | 1 |
| Two | 2 | 1 | 3 |
| Three | 1 | 0 | 1 |
| Four | 17 | 9 | 26 |
| Missing | 18 | 25 | 43 |
| In a current paid job Units: Subjects | | | |
| Yes | 58 | 74 | 132 |
| No | 55 | 42 | 97 |
| Missing | 3 | 2 | 5 |
| Typical weekly working hours | | | |

| | | | |
|---|-----|-----|-----|
| Units: Subjects | | | |
| N/A | 55 | 42 | 97 |
| Full time | 39 | 47 | 86 |
| Part time | 18 | 27 | 45 |
| Missing | 4 | 2 | 6 |
| Describes current situation in respect of your job | | | |
| Units: Subjects | | | |
| N/A | 55 | 42 | 97 |
| Doing my usual job | 50 | 62 | 112 |
| On paid annual leave/holiday | 2 | 1 | 3 |
| Working fewer hours | 1 | 2 | 3 |
| Doing lighter duties | 1 | 6 | 7 |
| On paid sick leave | 3 | 3 | 6 |
| On unpaid sick leave | 0 | 0 | 0 |
| Missing | 4 | 2 | 6 |
| If not doing usual job/annual leave, is this due to hand or wrist problems | | | |
| Units: Subjects | | | |
| N/A | 105 | 105 | 210 |
| Yes | 2 | 4 | 6 |
| No | 3 | 6 | 9 |
| Missing | 6 | 3 | 9 |
| Taken time off work during the last 6 months for your hand or wrist problem | | | |
| Units: Subjects | | | |
| N/A | 55 | 42 | 97 |
| Yes | 8 | 5 | 13 |
| No | 49 | 69 | 118 |
| Missing | 4 | 2 | 6 |
| I feel my welfare is important to my employer | | | |
| Units: Subjects | | | |
| N/A | 104 | 111 | 215 |
| Strongly disagree | 0 | 0 | 0 |
| Disagree | 0 | 0 | 0 |
| Agree | 4 | 3 | 7 |
| Strongly agree | 4 | 2 | 6 |
| Missing | 4 | 2 | 6 |
| Which treatment would you prefer | | | |
| Units: Subjects | | | |
| Strongly prefer wrist injection | 13 | 13 | 26 |
| Somewhat prefer wrist injection | 11 | 21 | 32 |
| No preference | 65 | 60 | 125 |
| Somewhat prefer night splints | 12 | 8 | 20 |
| Strongly prefer night splints | 6 | 10 | 16 |
| Missing | 9 | 6 | 15 |
| If you received wrist injection would you expect your symptoms to improve | | | |
| Units: Subjects | | | |
| Yes | 69 | 70 | 139 |
| No | 0 | 2 | 2 |
| Not sure | 39 | 41 | 80 |

| | | | |
|---|----|----|-----|
| Missing | 8 | 5 | 13 |
| If you received night splint would you expect your symptoms to improve Units: Subjects | | | |
| Yes | 46 | 40 | 86 |
| No | 3 | 4 | 7 |
| Not sure | 58 | 69 | 127 |
| Missing | 9 | 5 | 14 |
| My hand or wrist problem will last for a long time Units: Subjects | | | |
| Strongly disagree | 3 | 3 | 6 |
| Disagree | 7 | 8 | 15 |
| Neither agree nor disagree | 45 | 51 | 96 |
| Agree | 44 | 42 | 86 |
| Strongly agree | 14 | 12 | 26 |
| Missing | 3 | 2 | 5 |
| My hand or wrist problem has major consequences on my life Units: Subjects | | | |
| Strongly disagree | 4 | 10 | 14 |
| Disagree | 19 | 22 | 41 |
| Neither agree nor disagree | 26 | 30 | 56 |
| Agree | 41 | 37 | 78 |
| Strongly agree | 23 | 17 | 40 |
| Missing | 3 | 2 | 5 |
| There is a lot that I can do to control my hand or wrist problems Units: Subjects | | | |
| Strongly disagree | 12 | 9 | 21 |
| Disagree | 21 | 31 | 52 |
| Neither agree nor disagree | 48 | 42 | 90 |
| Agree | 30 | 32 | 62 |
| Strongly agree | 2 | 2 | 4 |
| Missing | 3 | 2 | 5 |
| What I can do determines whether my hand or wrist problem gets better or worse Units: Subjects | | | |
| Strongly disagree | 4 | 4 | 8 |
| Disagree | 11 | 14 | 25 |
| Neither agree nor disagree | 40 | 32 | 72 |
| Agree | 49 | 57 | 106 |
| Strongly agree | 9 | 9 | 18 |
| Missing | 3 | 2 | 5 |
| Treatment can control my hand or wrist problem Units: Subjects | | | |
| Strongly disagree | 0 | 0 | 0 |
| Disagree | 3 | 0 | 3 |
| Neither agree nor disagree | 20 | 35 | 55 |
| Agree | 74 | 71 | 145 |
| Strongly agree | 16 | 9 | 25 |
| Missing | 3 | 3 | 6 |

| | | | |
|---|-----|-----|-----|
| My hand or wrist problem affects me emotionally Units: Subjects | | | |
| Strongly disagree | 10 | 18 | 28 |
| Disagree | 17 | 19 | 36 |
| Neither agree nor disagree | 17 | 21 | 38 |
| Agree | 40 | 45 | 85 |
| Strongly agree | 29 | 13 | 42 |
| Missing | 3 | 2 | 5 |
| Been bothered by feeling down, depressed or hopeless Units: Subjects | | | |
| Yes | 47 | 39 | 86 |
| No | 66 | 78 | 144 |
| Missing | 3 | 1 | 4 |
| Been bothered by little interest or pleasure in doing things Units: Subjects | | | |
| Yes | 39 | 33 | 72 |
| No | 74 | 83 | 157 |
| Missing | 3 | 2 | 5 |
| Diagnosed with hypothyroidism Units: Subjects | | | |
| Yes | 5 | 9 | 14 |
| No | 108 | 107 | 215 |
| Missing | 3 | 2 | 5 |
| Diagnosed with diabetes Units: Subjects | | | |
| Yes | 13 | 8 | 21 |
| No | 99 | 109 | 208 |
| Missing | 4 | 1 | 5 |
| Any other conditions affecting neck, shoulders or elbows Units: Subjects | | | |
| Yes | 45 | 28 | 73 |
| No | 68 | 88 | 156 |
| Missing | 3 | 2 | 5 |
| Had pain anywhere else Units: Subjects | | | |
| Yes | 74 | 72 | 146 |
| No | 39 | 45 | 84 |
| Missing | 3 | 1 | 4 |
| Last time you were free of pain Units: Subjects | | | |
| <3 months ago | 22 | 20 | 42 |
| 3-6 months ago | 13 | 19 | 32 |
| 6 months-1 year | 9 | 23 | 32 |
| 1-3 years ago | 38 | 23 | 61 |
| >3 years ago | 31 | 32 | 63 |
| Missing | 3 | 1 | 4 |
| On average how often do you drink alcohol Units: Subjects | | | |

| | | | |
|---|----|-----|-----|
| Daily or most days | 11 | 11 | 22 |
| Once or twice a week | 38 | 45 | 83 |
| Once or twice a month | 25 | 22 | 47 |
| One or twice a year | 16 | 18 | 34 |
| Never | 23 | 21 | 44 |
| Missing | 3 | 1 | 4 |
| What is your current smoking status | | | |
| Units: Subjects | | | |
| Never smoked | 55 | 55 | 110 |
| Previously smoked | 39 | 48 | 87 |
| Current smoker | 19 | 13 | 32 |
| Missing | 3 | 2 | 5 |
| Insomnia due to hand or wrist problems | | | |
| Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. Based on multiply imputed data | | | |
| Units: Subjects | | | |
| No | 46 | 58 | 104 |
| Yes | 70 | 60 | 130 |
| Treatment for previous CTS: steroid injection | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 16 | 12 | 28 |
| Yes | 3 | 4 | 7 |
| Treatment for previous CTS: Wrist splint | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 12 | 12 | 24 |
| Yes | 7 | 4 | 11 |
| Treatment for previous CTS: carpal tunnel decompression | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 16 | 14 | 30 |
| Yes | 3 | 2 | 5 |
| Treatment for previous CTS: ultrasound | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 18 | 15 | 33 |
| Yes | 1 | 1 | 2 |
| Treatment for previous CTS: exercises | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 19 | 16 | 35 |
| Yes | 0 | 0 | 0 |
| Treatment for previous CTS: vitamin supplements | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 19 | 15 | 34 |
| Yes | 0 | 1 | 1 |
| Treatment for previous CTS: changes in | | | |

| | | | |
|--|-------|-------|-----|
| workplace | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 19 | 16 | 35 |
| Yes | 0 | 0 | 0 |
| Treatment for previous CTS: other | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 18 | 16 | 34 |
| Yes | 1 | 0 | 1 |
| Treatment for previous CTS: none | | | |
| Units: Subjects | | | |
| Not applicable | 97 | 102 | 199 |
| No | 14 | 8 | 22 |
| Yes | 5 | 8 | 13 |
| If not in a current paid job, describe current position: retired | | | |
| Units: Subjects | | | |
| Not applicable | 58 | 74 | 132 |
| No | 20 | 15 | 35 |
| Yes | 38 | 29 | 67 |
| If not in a current paid job, describe current position: student | | | |
| Units: Subjects | | | |
| Not applicable | 58 | 74 | 132 |
| No | 55 | 43 | 98 |
| Yes | 3 | 1 | 4 |
| If not in a current paid job, describe current position: looking after children/home | | | |
| Units: Subjects | | | |
| Not applicable | 58 | 74 | 132 |
| No | 46 | 35 | 81 |
| Yes | 12 | 9 | 21 |
| If not in a current paid job, describe current position: unemployed | | | |
| Units: Subjects | | | |
| Not applicable | 58 | 74 | 132 |
| No | 55 | 37 | 92 |
| Yes | 3 | 7 | 10 |
| If not in a current paid job, describe current position: voluntary worker | | | |
| Units: Subjects | | | |
| Not applicable | 58 | 74 | 132 |
| No | 56 | 44 | 100 |
| Yes | 2 | 0 | 2 |
| To what extent have hand or wrist problems affected your performance at work over the past month | | | |
| 0-10 scale; 0=not at all, 10=unable to do job | | | |
| Units: 0-10 scale | | | |
| arithmetic mean | 3.8 | 4.2 | |
| standard deviation | ± 3.0 | ± 2.9 | - |
| Body mass index | | | |

| | | | |
|--|--------|--------|---|
| Units: kg/m2 | | | |
| arithmetic mean | 30.2 | 30.5 | |
| standard deviation | ± 7.6 | ± 7.5 | - |
| BCTQ symptom severity and functional limitations | | | |
| Higher scores indicate more symptom severity and functional limitations. Based on multiply imputed data. BCTQ: Boston carpal tunnel questionnaire. | | | |
| Units: 1-5 | | | |
| arithmetic mean | 2.69 | 2.65 | |
| standard deviation | ± 0.70 | ± 0.62 | - |
| BCTQ symptom severity subscale | | | |
| Higher scores indicate more severe symptoms. Based on multiply imputed data. BCTQ: Boston carpal tunnel questionnaire. | | | |
| Units: 1-5 | | | |
| arithmetic mean | 2.96 | 2.91 | |
| standard deviation | ± 0.66 | ± 0.61 | - |
| BCTQ functional limitations subscale | | | |
| Higher scores indicate more severe functional impairment. Based on multiply imputed data. BCTQ: Boston carpal tunnel questionnaire. | | | |
| Units: 1-5 | | | |
| arithmetic mean | 2.32 | 2.28 | |
| standard deviation | ± 0.92 | ± 0.84 | - |
| Hand-wrist pain intensity | | | |
| Higher scores indicate more pain | | | |
| Units: 0-10 | | | |
| arithmetic mean | 6.33 | 6.12 | |
| standard deviation | ± 2.05 | ± 2.21 | - |

End points

End points reporting groups

| | |
|---|-------------------|
| Reporting group title | Steroid injection |
| Reporting group description: One injection of 20mg methylprednisolone acetate to infiltrate the carpal tunnel | |
| Reporting group title | Splint |
| Reporting group description: Participants received a beta wrist brace which immobilised the wrist in a neutral or slightly extended position intended to reduce pressure within the carpal tunnel, to wear at night for 6 weeks. | |

Primary: BCTQ symptom severity and functional limitations 6 weeks

| | |
|---|--|
| End point title | BCTQ symptom severity and functional limitations 6 weeks |
| End point description: Comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment). BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Primary |
| End point timeframe: 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.02 (\pm 0.81) | 2.29 (\pm 0.75) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Multiple imputation at 6 weeks |
| Statistical analysis description: Multiple imputation for missing data was performed at 6 weeks. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.32 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.48 |
| upper limit | -0.16 |

Secondary: BCTQ symptom severity subscale 6 weeks

| | |
|--|--|
| End point title | BCTQ symptom severity subscale 6 weeks |
| End point description: | |
| Comparison of BCTQ symptom severity between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms). | |
| BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.12 (\pm 0.84) | 2.43 (\pm 0.76) | | |

Statistical analyses

| | |
|--|--------------------------------|
| Statistical analysis title | Multiple imputation at 6 weeks |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 weeks. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.53 |
| upper limit | -0.17 |

Secondary: BCTQ functional limitations subscale 6 weeks

| | |
|-----------------|--|
| End point title | BCTQ functional limitations subscale 6 weeks |
|-----------------|--|

End point description:

Comparison of BCTQ functional limitations between treatment groups at 6 weeks follow-up (higher score indicates more severe functional impairment).

BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.88 (\pm 0.88) | 2.09 (\pm 0.86) | | |

Statistical analyses

| | |
|----------------------------|--------------------------------|
| Statistical analysis title | Multiple imputation at 6 weeks |
|----------------------------|--------------------------------|

Statistical analysis description:

Multiple imputation for missing data was performed at 6 weeks. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|-------------------|----------------------------|
| Comparison groups | Steroid injection v Splint |
|-------------------|----------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 234 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

| | |
|---------|---------|
| P-value | = 0.003 |
|---------|---------|

| | |
|--------|--------------------|
| Method | Regression, Linear |
|--------|--------------------|

| | |
|--------------------|--------------------------------|
| Parameter estimate | Mean difference (final values) |
|--------------------|--------------------------------|

| | |
|----------------|-------|
| Point estimate | -0.26 |
|----------------|-------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|-------|
| lower limit | -0.43 |
|-------------|-------|

| | |
|-------------|-------|
| upper limit | -0.09 |
|-------------|-------|

Secondary: Hand-wrist pain intensity 6 weeks

| | |
|-----------------|-----------------------------------|
| End point title | Hand-wrist pain intensity 6 weeks |
|-----------------|-----------------------------------|

End point description:

Comparison of pain scores between treatment groups at 6 weeks follow-up (higher score indicates more pain).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 3.42 (\pm 2.77) | 4.28 (\pm 2.73) | | |

Statistical analyses

| | |
|--|--------------------------------|
| Statistical analysis title | Multiple imputation at 6 weeks |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 weeks. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.64 |
| upper limit | -0.3 |

Secondary: Insomnia due to hand-wrist problems 6 weeks

| | |
|--|---|
| End point title | Insomnia due to hand-wrist problems 6 weeks |
| End point description: | |
| Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 83 | 73 | | |
| Yes | 33 | 45 | | |

Statistical analyses

| Statistical analysis title | Multiple imputation at 6 weeks |
|--|--------------------------------|
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 weeks. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.018 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.44 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.22 |
| upper limit | 0.87 |

Secondary: Referral to surgery at 6 weeks

| End point title | Referral to surgery at 6 weeks |
|---|--------------------------------|
| End point description: | |
| Participants were asked if they were referred for surgery (carpal tunnel decompression) in the last 6 weeks. | |
| Multiple imputation for missing data was planned at 6 weeks. Comparison of outcome between treatment arms planned to adjust for sex, age, and duration of symptoms. Logistic regression was not performed due to small number of `yes` counts | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 112 | 113 | | |
| Yes | 4 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Surgery 6 weeks

| | |
|--|-----------------|
| End point title | Surgery 6 weeks |
| End point description: | |
| Participants were asked if they had surgery for carpal tunnel syndrome in the last 6 weeks. | |
| Multiple imputation for missing data was planned at 6 weeks. Comparison of outcome between treatment arms planned to adjust for sex, age, and duration of symptoms. Logistic regression was not performed due to small number of `yes` counts. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 114 | 116 | | |
| Yes | 2 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: BCTQ symptom severity and functional limitations 6 months

| | |
|--|---|
| End point title | BCTQ symptom severity and functional limitations 6 months |
| End point description: | |
| Comparison of overall BCTQ between treatment groups at 6 months follow-up (higher score indicates more severe symptoms and functional impairment). | |
| BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.15 (\pm 0.79) | 2.06 (\pm 0.73) | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.11 |
| upper limit | 0.23 |

Secondary: BCTQ symptom severity subscale 6 months

| | |
|---|---|
| End point title | BCTQ symptom severity subscale 6 months |
| End point description: | |
| Comparison of BCTQ symptom severity between treatment groups at 6 months follow-up (higher score indicates more severe symptoms). | |
| BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.33 (\pm 0.86) | 2.18 (\pm 0.75) | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.21 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.07 |
| upper limit | 0.33 |

Secondary: BCTQ functional limitations subscale 6 months

| | |
|---|---|
| End point title | BCTQ functional limitations subscale 6 months |
| End point description: | |
| Comparison of BCTQ functional limitations between treatment groups at 6 months follow-up (higher score indicates more functional impairment). | |
| BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.91 (\pm 0.84) | 1.89 (\pm 0.84) | | |

Statistical analyses

| | |
|--|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.96 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.005 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.175 |
| upper limit | 0.166 |

Secondary: Hand-wrist pain intensity 6 months

| | |
|--|------------------------------------|
| End point title | Hand-wrist pain intensity 6 months |
| End point description: Comparison of pain scores between treatment groups at 6 months follow-up (higher score indicates more pain). | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 4.32 (\pm 3.26) | 3.46 (\pm 3.01) | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.055 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.79 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.02 |
| upper limit | 1.59 |

Secondary: Insomnia due to hand-wrist problems 6 months

| | |
|--|--|
| End point title | Insomnia due to hand-wrist problems 6 months |
| End point description: | |
| Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 79 | 86 | | |
| Yes | 37 | 32 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|----------------------|
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.76 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.55 |
| upper limit | 2.2 |

Secondary: Referral to surgery 6 months

| | |
|---|------------------------------|
| End point title | Referral to surgery 6 months |
| End point description: | |
| Participants were asked if they were referred for surgery (carpal tunnel decompression) in the last 6 months. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 94 | 104 | | |
| Yes | 22 | 14 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.23 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.66 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.73 |
| upper limit | 3.77 |

Secondary: Surgery 6 months

| | |
|--|------------------|
| End point title | Surgery 6 months |
| End point description: Participants were asked if they had surgery for carpal tunnel syndrome in the last 6 months. | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 99 | 105 | | |
| Yes | 17 | 13 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: Multiple imputation for missing data was performed at 6 months. Comparison of outcome between the treatment groups were adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.66 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.28 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.41 |
| upper limit | 3.98 |

Secondary: Herbal remedies and vitamin use 6 months

| | |
|---|--|
| End point title | Herbal remedies and vitamin use 6 months |
| End point description: Participants were asked if they had bought herbal remedies or vitamins to help with hand or wrist problems in the last 6 months | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 109 | 111 | | |
| Yes | 7 | 7 | | |

Statistical analyses

| | |
|--|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.66 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.28 |
| upper limit | 7.34 |

Secondary: Over the counter pain medication 6 months

| | |
|--|---|
| End point title | Over the counter pain medication 6 months |
| End point description: Participants were asked if they bought over the counter paracetamol, ibuprofen or co-codamol to help with hand or wrist problems in the last 6 months. | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 82 | 88 | | |
| Yes | 34 | 30 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.42 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.63 |
| upper limit | 3.18 |

Secondary: Prescribed pain medication 6 months

| | |
|---|-------------------------------------|
| End point title | Prescribed pain medication 6 months |
| End point description: | |
| Participants were asked if they were prescribed tablet medication (paracetamol, ibuprofen, naproxen, diclofenac, codeine, tramadol, co-codamol, tramacet, co-proxamol, dihydrocodeine, other) for hand or wrist problem in the last 6 months. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 2 categories | | | | |
| No | 96 | 106 | | |
| Yes | 20 | 12 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Multiple imputation at 6 months |
| Statistical analysis description: | |
| Multiple imputation for missing data was performed at 6 months. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 5.66 |

Secondary: BCTQ symptom severity and functional limitations over 24 months: 6 weeks

| | |
|---|--|
| End point title | BCTQ symptom severity and functional limitations over 24 months: 6 weeks |
| End point description: | |
| Comparison of overall BCTQ between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more severe symptoms and functional impairment). Results are presented at 6 weeks. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 95 | 102 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.95 (\pm 0.82) | 2.30 (\pm 0.77) | | |

Statistical analyses

| Statistical analysis title | Available case analysis |
|---|--------------------------------|
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.34 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.53 |
| upper limit | -0.14 |

Secondary: BCTQ symptom severity and functional limitations over 24 months: 6 months

| | |
|---|---|
| End point title | BCTQ symptom severity and functional limitations over 24 months: 6 months |
| End point description: | |
| Comparison of overall BCTQ between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more severe symptoms and functional impairment). Results are presented at 6 months. BCTQ: Boston Carpal Tunnel Questionnaire. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 92 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.08 (\pm 0.79) | 2.04 (\pm 0.72) | | |

Statistical analyses

| Statistical analysis title | Available case analysis |
|---|--------------------------------|
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Splint v Steroid injection |
| Number of subjects included in analysis | 175 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.74 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.17 |
| upper limit | 0.24 |

Secondary: BCTQ symptom severity and functional limitations over 24 months: 12 months

| | |
|--|--|
| End point title | BCTQ symptom severity and functional limitations over 24 months: 12 months |
| End point description: | |
| Comparison of overall BCTQ between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more severe symptoms and functional impairment). Results are presented at 12 months. BCTQ: Boston Carpal Tunnel Questionnaire. | |
| End point type | Secondary |
| End point timeframe: | |
| 12 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 78 | 78 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.98 (\pm 0.88) | 2.05 (\pm 0.80) | | |

Statistical analyses

| Statistical analysis title | Available case analysis |
|---|--------------------------------|
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 156 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.41 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.09 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.3 |
| upper limit | 0.12 |

Secondary: BCTQ symptom severity and functional limitations over 24 months: 24 months

| | |
|---|--|
| End point title | BCTQ symptom severity and functional limitations over 24 months: 24 months |
| End point description: | |
| Comparison of overall BCTQ between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more severe symptoms and functional impairment). Results are presented at 24 months. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 24 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 70 | 73 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.79 (\pm 0.79) | 1.73 (\pm 0.76) | | |

Statistical analyses

| Statistical analysis title | Available case analysis |
|---|--------------------------------|
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 143 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.58 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.16 |
| upper limit | 0.28 |

Secondary: Hand-wrist pain intensity over 24 months: 6 weeks

| | |
|--|---|
| End point title | Hand-wrist pain intensity over 24 months: 6 weeks |
| End point description: | |
| Comparison of pain scores between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more pain). Results are presented at 6 weeks. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 105 | 106 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 3.33 (\pm 2.67) | 4.28 (\pm 2.62) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Available case analysis |
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 211 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.009 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.72 |
| upper limit | -0.24 |

Secondary: Hand-wrist pain intensity over 24 months: 6 months

| | |
|---|--|
| End point title | Hand-wrist pain intensity over 24 months: 6 months |
| End point description: | |
| Comparison of pain scores between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more pain). Results are presented at 6 months. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 92 | 94 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 4.11 (\pm 3.01) | 3.29 (\pm 2.74) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Available case analysis |
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.058 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.02 |
| upper limit | 1.54 |

Secondary: Hand-wrist pain intensity over 24 months: 12 months

| | |
|--|---|
| End point title | Hand-wrist pain intensity over 24 months: 12 months |
| End point description: | |
| Comparison of pain scores between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more pain). Results are presented at 12 months. | |
| End point type | Secondary |
| End point timeframe: | |
| 12 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 85 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 3.17 (± 2.93) | 3.14 (± 2.74) | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Available case analysis |
| Statistical analysis description: | |
| Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 168 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.95 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.79 |
| upper limit | 0.85 |

Secondary: Hand-wrist pain intensity over 24 months: 24 months

| | |
|------------------------|---|
| End point title | Hand-wrist pain intensity over 24 months: 24 months |
| End point description: | Comparison of pain scores between treatment groups across all time points (6 weeks, 6-, 12-, and 24 month follow-up) (higher score indicates more pain). Results were presented at 24 months. |
| End point type | Secondary |
| End point timeframe: | 24 months |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 75 | 77 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 2.81 (± 3.19) | 2.40 (± 2.83) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Available case analysis |
| Statistical analysis description: | Available case analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. An interaction term was fitted between treatment and follow-up time point to estimate treatment effect at each time point. |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 152 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.35 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.41 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.45 |
| upper limit | 1.26 |

Secondary: BCTQ symptom severity and functional limitations 6 weeks (CC)

| | |
|--|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (CC) |
| End point description: | |
| Sensitivity analysis for comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 95 | 102 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.95 (± 0.82) | 2.29 (± 0.77) | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Complete case analysis at 6 weeks |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 197 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.54 |
| upper limit | -0.19 |

Secondary: BCTQ symptom severity subscale 6 weeks (CC)

| | |
|-----------------|---|
| End point title | BCTQ symptom severity subscale 6 weeks (CC) |
|-----------------|---|

End point description:

Sensitivity analysis for comparison of BCTQ symptom severity between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 104 | 104 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.07 (\pm 0.83) | 2.44 (\pm 0.78) | | |

Statistical analyses

| | |
|----------------------------|-----------------------------------|
| Statistical analysis title | Complete case analysis at 6 weeks |
|----------------------------|-----------------------------------|

Statistical analysis description:

Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|---|--------------------------------|
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 208 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.59 |
| upper limit | -0.21 |

Secondary: BCTQ functional limitations subscale 6 weeks (CC)

| | |
|-----------------|---|
| End point title | BCTQ functional limitations subscale 6 weeks (CC) |
|-----------------|---|

End point description:

Sensitivity analysis for comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more functional impairment) on participants with complete data. BCTQ: Boston

Carpal Tunnel Questionnaire

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 96 | 105 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.86 (\pm 0.91) | 2.10 (\pm 0.86) | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Complete case analysis at 6 weeks |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 201 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.44 |
| upper limit | -0.08 |

Secondary: Hand-wrist pain intensity 6 weeks (CC)

| | |
|--|--|
| End point title | Hand-wrist pain intensity 6 weeks (CC) |
| End point description: | |
| Sensitivity analysis for comparison of pain scores between treatment groups at 6 weeks follow-up (higher score indicates more pain) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 105 | 106 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 3.33 (\pm 2.67) | 4.28 (\pm 2.62) | | |

Statistical analyses

| Statistical analysis title | Complete case analysis at 6 weeks |
|---|-----------------------------------|
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 211 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.72 |
| upper limit | -0.38 |

Secondary: Insomnia due to hand-wrist problems 6 weeks (CC)

| | |
|--|--|
| End point title | Insomnia due to hand-wrist problems 6 weeks (CC) |
| End point description: | |
| Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. Sensitivity analysis for comparison of the odds of insomnia between treatment groups at 6 weeks follow-up on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 97 | 96 | | |
| Units: 2 categories | | | | |
| No | 75 | 62 | | |
| Yes | 22 | 34 | | |

Statistical analyses

| | |
|--|-----------------------------------|
| Statistical analysis title | Complete case analysis at 6 weeks |
| Statistical analysis description: Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 193 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.006 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.17 |
| upper limit | 0.74 |

Secondary: BCTQ symptom severity and functional limitations 6 months (CC)

| | |
|---|--|
| End point title | BCTQ symptom severity and functional limitations 6 months (CC) |
| End point description: Sensitivity analysis for comparison of overall BCTQ between treatment groups at 6 months follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 92 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.08 (± 0.79) | 2.04 (± 0.72) | | |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Splint v Steroid injection |
| Number of subjects included in analysis | 175 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.58 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.13 |
| upper limit | 0.24 |

Secondary: BCTQ symptom severity 6 months (CC)

| | |
|--|-------------------------------------|
| End point title | BCTQ symptom severity 6 months (CC) |
| End point description: | |
| Sensitivity analysis for comparison of BCTQ symptom severity between treatment groups at 6 months follow-up (higher score indicates more severe symptoms) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 88 | 94 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.29 (± 0.87) | 2.16 (± 0.74) | | |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 182 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.25 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.09 |
| upper limit | 0.35 |

Secondary: BCTQ functional limitations subscale 6 months (CC)

| | |
|--|--|
| End point title | BCTQ functional limitations subscale 6 months (CC) |
| End point description: | |
| Sensitivity analysis for comparison of BCTQ function limitations between treatment groups at 6 months follow-up (higher score indicates more functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 85 | 93 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.85 (± 0.84) | 1.88 (± 0.82) | | |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 178 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.93 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.01 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.17 |
| upper limit | 0.18 |

Secondary: Hand-wrist pain intensity 6 months (CC)

| | |
|--|---|
| End point title | Hand-wrist pain intensity 6 months (CC) |
| End point description: Sensitivity analysis for comparison of pain scores between treatment groups at 6 months follow-up (higher score indicates more pain) on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 92 | 94 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 4.11 (\pm 3.01) | 3.29 (\pm 2.74) | | |

Statistical analyses

| | |
|--|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 186 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.052 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.01 |
| upper limit | 1.61 |

Secondary: Insomnia due to hand-wrist problems 6 months (CC)

| | |
|-----------------|---|
| End point title | Insomnia due to hand-wrist problems 6 months (CC) |
|-----------------|---|

End point description:

Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. Sensitivity analysis for comparison of the odds of insomnia between treatment groups at 6 months follow-up on participants with complete data.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 86 | | |
| Units: 2 categories | | | | |
| No | 60 | 68 | | |
| Yes | 20 | 18 | | |

Statistical analyses

| | |
|----------------------------|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
|----------------------------|------------------------------------|

Statistical analysis description:

Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|-------------------|----------------------------|
| Comparison groups | Steroid injection v Splint |
|-------------------|----------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 166 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

| | |
|---------|--------|
| P-value | = 0.53 |
|---------|--------|

| | |
|--------|----------------------|
| Method | Regression, Logistic |
|--------|----------------------|

| | |
|--------------------|-----------------|
| Parameter estimate | Odds ratio (OR) |
|--------------------|-----------------|

| | |
|----------------|------|
| Point estimate | 1.29 |
|----------------|------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|------|
| lower limit | 0.58 |
|-------------|------|

| | |
|-------------|------|
| upper limit | 2.88 |
|-------------|------|

Secondary: Referral to surgery 6 months (CC)

| | |
|-----------------|-----------------------------------|
| End point title | Referral to surgery 6 months (CC) |
|-----------------|-----------------------------------|

End point description:

Participants were asked if they were referred for surgery (carpal tunnel decompression) in the last 6 months. Sensitivity analysis for comparison of the odds of insomnia between treatment groups at 6 months follow-up on participants with complete data.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 96 | 93 | | |
| Units: 2 categories | | | | |
| No | 80 | 82 | | |
| Yes | 16 | 11 | | |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 189 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.41 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.61 |
| upper limit | 3.34 |

Secondary: Herbal remedies and vitamin use 6 months (CC)

| | |
|--|---|
| End point title | Herbal remedies and vitamin use 6 months (CC) |
| End point description: | |
| Participants were asked if they had bought herbal remedies or vitamins to help with hand or wrist problems in the last 6 months. Sensitivity analysis for comparison of the odds of herbal remedies and vitamin use between treatment groups at 6 months follow-up on participants with complete data. | |
| Complete case analysis as a sensitivity analysis was planned. Comparison of outcome between treatment arms planned to adjust for sex, age, and duration of symptoms. Logistic regression was not performed due to small number of 'yes' counts. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 83 | | |
| Units: 2 categories | | | | |
| No | 78 | 81 | | |
| Yes | 2 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Over the counter pain medication 6 months (CC)

| | |
|---|--|
| End point title | Over the counter pain medication 6 months (CC) |
| End point description: | |
| Participants were asked if they bought over the counter paracetamol, ibuprofen or co-codamol to help with hand or wrist problems in the last 6 months. Sensitivity analysis for comparison of the odds of medication use between treatment groups at 6 months follow-up on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 83 | | |
| Units: 2 categories | | | | |
| No | 64 | 66 | | |
| Yes | 16 | 17 | | |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|----------------------|
| Number of subjects included in analysis | 163 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.52 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.32 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.57 |
| upper limit | 3.06 |

Secondary: Prescribed pain medication 6 months (CC)

| | |
|---|--|
| End point title | Prescribed pain medication 6 months (CC) |
| End point description: | |
| Participants were asked if they were prescribed tablet medication (paracetamol, ibuprofen, naproxen, diclofenac, codeine, tramadol, co-codomal, tramacet, co-proxamol, dihydrocodeine, other) for hand or wrist problem in the last 6 months. Sensitivity analysis for comparison of the odds of pain medication use between treatment groups at 6 months follow-up on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 82 | 86 | | |
| Units: 2 categories | | | | |
| No | 70 | 79 | | |
| Yes | 12 | 7 | | |

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Complete case analysis at 6 months |
| Statistical analysis description: | |
| Complete case analysis as a sensitivity analysis was performed. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|----------------------|
| Number of subjects included in analysis | 168 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.18 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.72 |
| upper limit | 5.78 |

Secondary: BCTQ symptom severity and functional limitations 6 weeks (PR)

| | |
|---|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (PR) |
| End point description: | |
| Per protocol analysis for comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 94 | 85 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.96 (± 0.84) | 2.28 (± 0.72) | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 weeks |
| Statistical analysis description: | |
| Per protocol analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Splint v Steroid injection |
| Number of subjects included in analysis | 179 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.36 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.55 |
| upper limit | -0.18 |

Secondary: BCTQ symptom severity 6 weeks (PR)

| | |
|--|------------------------------------|
| End point title | BCTQ symptom severity 6 weeks (PR) |
| End point description: | |
| Per protocol analysis for comparison of BCTQ symptom severity between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 102 | 86 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.07 (\pm 0.83) | 2.44 (\pm 0.74) | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 weeks |
| Statistical analysis description: | |
| Per protocol analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 188 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.39 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.59 |
| upper limit | -0.19 |

Secondary: BCTQ functional limitations subscale 6 weeks (PR)

| | |
|-----------------|---|
| End point title | BCTQ functional limitations subscale 6 weeks (PR) |
|-----------------|---|

End point description:

Per protocol analysis for comparison of BCTQ functional limitations between treatment groups at 6 weeks follow-up (higher score indicates more functional impairment) on participants with complete data.
BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 95 | 87 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.88 (\pm 0.94) | 2.06 (\pm 0.80) | | |

Statistical analyses

| | |
|----------------------------|----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 weeks |
|----------------------------|----------------------------------|

Statistical analysis description:

Per protocol analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|-------------------|----------------------------|
| Comparison groups | Steroid injection v Splint |
|-------------------|----------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 182 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

| | |
|---------|---------|
| P-value | = 0.003 |
|---------|---------|

| | |
|--------|--------------------|
| Method | Regression, Linear |
|--------|--------------------|

| | |
|--------------------|--------------------------------|
| Parameter estimate | Mean difference (final values) |
|--------------------|--------------------------------|

| | |
|----------------|-------|
| Point estimate | -0.28 |
|----------------|-------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|-------|
| lower limit | -0.46 |
|-------------|-------|

| | |
|-------------|-------|
| upper limit | -0.09 |
|-------------|-------|

Secondary: Hand-wrist pain intensity 6 weeks (PR)

| | |
|-----------------|--|
| End point title | Hand-wrist pain intensity 6 weeks (PR) |
|-----------------|--|

End point description:

Per protocol analysis for comparison of pain scores between treatment groups at 6 weeks follow-up (higher score indicates more pain) on participants with complete data.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 103 | 87 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 3.33 (\pm 2.67) | 4.44 (\pm 2.50) | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 weeks |
| Statistical analysis description: | |
| Per protocol analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 190 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -1.16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.85 |
| upper limit | -0.48 |

Secondary: Insomnia due to hand-wrist problems 6 weeks (PR)

| | |
|---|--|
| End point title | Insomnia due to hand-wrist problems 6 weeks (PR) |
| End point description: | |
| Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. Per protocol analysis for comparison of the odds of insomnia between treatment groups at 6 weeks follow-up on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 95 | 87 | | |
| Units: 2 categories | | | | |
| No | 74 | 57 | | |
| Yes | 21 | 30 | | |

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 weeks |
| Statistical analysis description: | |
| Per protocol analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 182 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.007 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.34 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.16 |
| upper limit | 0.74 |

Secondary: BCTQ symptom severity and functional limitations 6 months (PR)

| | |
|--|--|
| End point title | BCTQ symptom severity and functional limitations 6 months (PR) |
| End point description: | |
| Per protocol analysis for comparison of overall BCTQ between treatment groups at 6 months follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 76 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.09 (± 0.79) | 2.02 (± 0.69) | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 159 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.63 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.15 |
| upper limit | 0.25 |

Secondary: BCTQ symptom severity 6 months (PR)

| | |
|---|-------------------------------------|
| End point title | BCTQ symptom severity 6 months (PR) |
| End point description: | |
| Per protocol analysis for comparison of BCTQ symptom severity between treatment groups at 6 months follow-up (higher score indicates more severe symptoms) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 88 | 78 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.28 (\pm 0.86) | 2.15 (\pm 0.73) | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 166 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.28 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.1 |
| upper limit | 0.35 |

Secondary: BCTQ functional limitations subscale 6 months (PR)

| | |
|---|--|
| End point title | BCTQ functional limitations subscale 6 months (PR) |
| End point description: | |
| Per protocol analysis for comparison of BCTQ functional limitations between treatment groups at 6 months follow-up (higher score indicates more functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 85 | 77 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.89 (± 0.87) | 1.84 (± 0.77) | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 162 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.9 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.01 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.18 |
| upper limit | 0.2 |

Secondary: Hand-wrist pain intensity 6 months (PR)

| | |
|---|---|
| End point title | Hand-wrist pain intensity 6 months (PR) |
| End point description: | |
| Per protocol analysis for comparison of pain scores between treatment groups at 6 months follow-up (higher score indicates more pain) on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 92 | 78 | | |
| Units: 0-10 | | | | |
| arithmetic mean (standard deviation) | 4.11 (± 2.99) | 3.38 (± 2.79) | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 170 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.09 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.74 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.11 |
| upper limit | 1.59 |

Secondary: Insomnia due to hand-wrist problems 6 months (PR)

| | |
|--|---|
| End point title | Insomnia due to hand-wrist problems 6 months (PR) |
| End point description: | |
| Participants were asked four questions how hand and wrist problems affects their sleep. Participants reporting hand and wrist problems affects their sleep on most nights on one or more questions were deemed to have insomnia. Per protocol analysis for comparison of the odds of insomnia between treatment groups at 6 months follow-up on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 81 | 75 | | |
| Units: 2 categories | | | | |
| No | 61 | 59 | | |
| Yes | 20 | 16 | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 156 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.58 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.56 |
| upper limit | 2.85 |

Secondary: Referral to surgery at 6 months (PR)

| | |
|-----------------|--------------------------------------|
| End point title | Referral to surgery at 6 months (PR) |
|-----------------|--------------------------------------|

End point description:

Participants were asked if they were referred for surgery (carpal tunnel decompression) in the last 6 months. Per protocol analysis for comparison of the odds of insomnia between treatment groups at 6 months follow-up on participants with complete data.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 94 | 85 | | |
| Units: 2 categories | | | | |
| No | 78 | 74 | | |
| Yes | 16 | 11 | | |

Statistical analyses

| | |
|-----------------------------------|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
|-----------------------------------|-----------------------------------|

Statistical analysis description:

Per protocol analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms.

| | |
|-------------------|----------------------------|
| Comparison groups | Splint v Steroid injection |
|-------------------|----------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 179 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

| | |
|---------|--------|
| P-value | = 0.52 |
|---------|--------|

| | |
|--------|----------------------|
| Method | Regression, Logistic |
|--------|----------------------|

| | |
|--------------------|-----------------|
| Parameter estimate | Odds ratio (OR) |
|--------------------|-----------------|

| | |
|----------------|------|
| Point estimate | 1.31 |
|----------------|------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|------|
| lower limit | 0.57 |
|-------------|------|

| | |
|-------------|------|
| upper limit | 3.01 |
|-------------|------|

Secondary: Herbal remedies and vitamin use 6 months (PR)

| | |
|-----------------|---|
| End point title | Herbal remedies and vitamin use 6 months (PR) |
|-----------------|---|

End point description:

Participants were asked if they had bought herbal remedies or vitamins to help with hand or wrist problems in the last 6 months. Per protocol analysis for comparison of the odds of herbal remedies and vitamin use between treatment groups at 6 months follow-up on participants with complete data.

Per protocol analysis on complete date was planned. Comparison of outcome between treatment arms planned to adjust for sex, age, and duration of symptoms. Logistic regression was not performed due to small number of 'yes' counts.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 81 | 73 | | |
| Units: 2 categories | | | | |
| No | 78 | 72 | | |
| Yes | 3 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Over the counter pain medication 6 months (PR)

| | |
|-----------------|--|
| End point title | Over the counter pain medication 6 months (PR) |
|-----------------|--|

End point description:

Participants were asked if they bought over the counter paracetamol, ibuprofen or co-codamol to help with hand or wrist problems in the last 6 months. Per protocol analysis for comparison of the odds of medication use between treatment groups at 6 months follow-up on participants with complete data.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 81 | 73 | | |
| Units: 2 categories | | | | |
| No | 65 | 58 | | |
| Yes | 16 | 15 | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 154 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.61 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.53 |
| upper limit | 2.95 |

Secondary: Prescribed pain medication 6 months (PR)

| | |
|---|--|
| End point title | Prescribed pain medication 6 months (PR) |
| End point description: | |
| Participants were asked if they were prescribed tablet medication (paracetamol, ibuprofen, naproxen, diclofenac, codeine, tramadol, co-codomal, tramacet, co-proxamol, dihydrocodeine, other) for hand or wrist problem in the last 6 months. Per protocol analysis for comparison of the odds of medication use between treatment groups at 6 months follow-up on participants with complete data. | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|-----------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 76 | | |
| Units: 2 categories | | | | |
| No | 70 | 70 | | |
| Yes | 13 | 6 | | |

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Per protocol analysis at 6 months |
| Statistical analysis description: | |
| Per protocol analysis on complete date was performed. Comparison of outcome between treatment arms was adjusted for sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|----------------------------|
| Number of subjects included in analysis | 159 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[1] |
| P-value | = 0.14 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2.24 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.77 |
| upper limit | 6.58 |

Notes:

[1] - Logistic regression was not performed due to small number of 'yes' counts.

Secondary: BCTQ symptom severity and functional limitations 6 weeks (SG)

| | |
|-----------------|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (SG) |
|-----------------|---|

End point description:

Subgroup analysis was performed in patients who were allocated the intervention of their preference. Comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 18 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.88 (± 0.76) | 2.19 (± 0.75) | | |

Statistical analyses

| | |
|----------------------------|------------------------------|
| Statistical analysis title | Subgroup analysis at 6 weeks |
|----------------------------|------------------------------|

Statistical analysis description:

Sub group analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|---|--------------------------------|
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 42 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.014 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.52 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.93 |
| upper limit | -0.12 |

Secondary: BCTQ symptom severity and functional limitations 6 weeks (SG)

| | |
|---|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (SG) |
| End point description: | |
| Subgroup analysis was performed in patients who did not receive the intervention of their preference. Comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire | |
| End point type | Secondary |
| End point timeframe: | |
| 6 weeks | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 34 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.15 (± 0.91) | 2.40 (± 0.84) | | |

Statistical analyses

| | |
|--|--------------------------------|
| Statistical analysis title | Subgroup analysis at 6 weeks |
| Statistical analysis description: | |
| Sub group analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.53 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.5 |
| upper limit | 0.26 |

Secondary: BCTQ symptom severity and functional limitations 6 weeks (SG)

| | |
|-----------------|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (SG) |
|-----------------|---|

End point description:

Subgroup analysis was performed in patients who did not state a preference of intervention. Comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 67 | 61 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.03 (\pm 0.79) | 2.26 (\pm 0.69) | | |

Statistical analyses

| | |
|----------------------------|------------------------------|
| Statistical analysis title | Subgroup analysis at 6 weeks |
|----------------------------|------------------------------|

Statistical analysis description:

Sub group analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|---|--------------------------------|
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 128 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.015 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.24 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.44 |
| upper limit | -0.05 |

Secondary: BCTQ symptom severity and functional limitations 6 weeks (SG)

| | |
|-----------------|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (SG) |
|-----------------|---|

End point description:

Subgroup analysis was performed in patients who preferred injection. Comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 34 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 1.88 (\pm 0.76) | 2.40 (\pm 0.84) | | |

Statistical analyses

| | |
|----------------------------|------------------------------|
| Statistical analysis title | Subgroup analysis at 6 weeks |
|----------------------------|------------------------------|

Statistical analysis description:

Sub group analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms.

| | |
|---|--------------------------------|
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 58 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.97 |
| upper limit | -0.23 |

Secondary: BCTQ symptom severity and functional limitations 6 weeks (SG)

| | |
|-----------------|---|
| End point title | BCTQ symptom severity and functional limitations 6 weeks (SG) |
|-----------------|---|

End point description:

Subgroup analysis was performed in patients who preferred splint. Comparison of overall BCTQ between treatment groups at 6 weeks follow-up (higher score indicates more severe symptoms and functional impairment) on participants with complete data. BCTQ: Boston Carpal Tunnel Questionnaire

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 weeks

| End point values | Steroid injection | Splint | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 18 | 34 | | |
| Units: 1-5 | | | | |
| arithmetic mean (standard deviation) | 2.15 (\pm 0.91) | 2.40 (\pm 0.84) | | |

Statistical analyses

| Statistical analysis title | Subgroup analysis at 6 weeks |
|--|--------------------------------|
| Statistical analysis description: | |
| Sub group analysis on complete data was performed. Comparison of outcome between treatment arms was adjusted for baseline score, sex, age, and duration of symptoms. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 52 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.25 |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.6 |
| upper limit | 0.16 |

Secondary: NHS cost differences at 6 months

| End point title | NHS cost differences at 6 months |
|-----------------------------------|----------------------------------|
| End point description: | |
| Cost of interventions at 6 months | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-infinity | | | | |
| arithmetic mean (standard deviation) | 346.78 (\pm 467.97) | 313.24 (\pm 480.84) | | |

Statistical analyses

| Statistical analysis title | Health economics analysis |
|---|--------------------------------|
| Statistical analysis description: | |
| Comparison of outcome between treatment groups performed on multiply imputed data | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 33.54 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -94.57 |
| upper limit | 145.59 |

Secondary: NHS cost differences at 6 months (CC)

| | |
|---|---------------------------------------|
| End point title | NHS cost differences at 6 months (CC) |
| End point description: | |
| Complete case analysis on the cost of interventions at 6 months | |
| End point type | Secondary |
| End point timeframe: | |
| 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-infinity | | | | |
| arithmetic mean (standard deviation) | 353.48 (\pm 512.85) | 306.42 (\pm 524.51) | | |

Statistical analyses

| | |
|--|--------------------------------|
| Statistical analysis title | Health economics analysis |
| Statistical analysis description: | |
| Comparison of outcome between treatment groups on complete data. | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 47.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -104.84 |
| upper limit | 187.31 |

Secondary: NHS cost differences at 12 months

| | |
|-----------------------------------|-----------------------------------|
| End point title | NHS cost differences at 12 months |
| End point description: | |
| Cost of interventions at 6 months | |
| End point type | Secondary |
| End point timeframe: | |
| 12 months | |

| | | | | |
|--------------------------------------|------------------------|------------------------|--|--|
| End point values | Steroid injection | Splint | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-infinity | | | | |
| arithmetic mean (standard deviation) | 508.69 (\pm 657.48) | 395.54 (\pm 596.47) | | |

Statistical analyses

| | |
|--|----------------------------|
| Statistical analysis title | Health economics analysis |
| Statistical analysis description: | |
| Comparison of outcome between treatment groups | |
| Comparison groups | Steroid injection v Splint |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 113.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -37.09 |
| upper limit | 279.21 |

Secondary: NHS cost differences at 24 months

| | |
|------------------------------------|-----------------------------------|
| End point title | NHS cost differences at 24 months |
| End point description: | |
| Cost of interventions at 24 months | |
| End point type | Secondary |
| End point timeframe: | |
| 24 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-infinity | | | | |
| arithmetic mean (standard deviation) | 657.87 (± 808.57) | 586.77 (± 783.45) | | |

Statistical analyses

| | |
|--|--------------------------------|
| Statistical analysis title | Health economics analysis |
| Statistical analysis description: | |
| Comparison of outcome between treatment groups | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 71.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -120.84 |
| upper limit | 291.24 |

Secondary: QALYS at 6 months (cross-walk tariff)

| | |
|---|---------------------------------------|
| End point title | QALYS at 6 months (cross-walk tariff) |
| End point description: QALYS (Quality adjusted life years) | |
| End point type | Secondary |
| End point timeframe: 6 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-1 | | | | |
| arithmetic mean (standard deviation) | 0.354 (± 0.093) | 0.356 (± 0.087) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Health economics analysis |
| Statistical analysis description: Comparison of outcome between treatment groups adjusted for baseline utility | |
| Comparison groups | Splint v Steroid injection |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.008 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.01 |
| upper limit | 0.02 |

Secondary: QALYS at 12 months (cross-walk tariff)

| | |
|-----------------|--|
| End point title | QALYS at 12 months (cross-walk tariff) |
|-----------------|--|

| | |
|---|-----------|
| End point description: QALYS (Quality adjusted life years) | |
| End point type | Secondary |
| End point timeframe: 12 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-1 | | | | |
| arithmetic mean (standard deviation) | 0.723 (\pm 0.163) | 0.736 (\pm 0.156) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Health economics analysis |
| Statistical analysis description: Comparison of outcome between treatment groups adjusted for baseline utility | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.003 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.034 |
| upper limit | 0.027 |

Secondary: QALYS at 24 months (cross-walk tariff)

| | |
|-----------------------------------|--|
| End point title | QALYS at 24 months (cross-walk tariff) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: 24 months | |

| End point values | Steroid injection | Splint | | |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 116 | 118 | | |
| Units: 0-1 | | | | |
| arithmetic mean (standard deviation) | 1.461 (± 0.311) | 1.497 (± 0.301) | | |

Statistical analyses

| Statistical analysis title | Health economics analysis |
|--|--------------------------------|
| Statistical analysis description: | |
| Comparison of outcome between treatment groups adjusted for baseline utility | |
| Comparison groups | Steroid injection v Splint |
| Number of subjects included in analysis | 234 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Regression, Linear |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.022 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.093 |
| upper limit | 0.045 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

24 months

Adverse event reporting additional description:

Reporting by investigators. Expected related adverse events self-reported by participants in 6-week questionnaire

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|-------|
| Dictionary name | CTCAE |
|-----------------|-------|

| | |
|--------------------|-----|
| Dictionary version | 4.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|-------------------|
| Reporting group title | Steroid injection |
|-----------------------|-------------------|

Reporting group description:

One injection of 20mg methylprednisolone acetate to infiltrate the carpal tunnel

| | |
|-----------------------|--------|
| Reporting group title | Splint |
|-----------------------|--------|

Reporting group description:

Participants received a beta wrist brace which immobilised the wrist in a neutral or slightly extended position intended to reduce pressure within the carpal tunnel, to wear at night for 6 weeks.

| Serious adverse events | Steroid injection | Splint | |
|---|--|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 116 (2.59%) | 4 / 118 (3.39%) | |
| number of deaths (all causes) | 2 | 0 | |
| number of deaths resulting from adverse events | 2 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Fracture | Additional description: Open comminuted fracture left middle finger, operative fixation with K-wires | | |
| subjects affected / exposed | 0 / 116 (0.00%) | 1 / 118 (0.85%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 116 (0.86%) | 0 / 118 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myocardial infarction | | | |

| | | | |
|---|---|-----------------|--|
| subjects affected / exposed | 0 / 116 (0.00%) | 1 / 118 (0.85%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Other | Additional description: Cryptogenic organising pneumonia | | |
| subjects affected / exposed | 1 / 116 (0.86%) | 0 / 118 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Other | Additional description: Patella resurfacing | | |
| subjects affected / exposed | 1 / 116 (0.86%) | 0 / 118 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | Additional description: Total arthroplasty for osteoarthritis (one hip, one knee) | | |
| subjects affected / exposed | 0 / 116 (0.00%) | 2 / 118 (1.69%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Steroid injection | Splint | |
|---|---|-----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 57 / 116 (49.14%) | 7 / 118 (5.93%) | |
| Vascular disorders | | | |
| Flushing | | | |
| subjects affected / exposed | 17 / 116 (14.66%) | 0 / 118 (0.00%) | |
| occurrences (all) | 17 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Other | Additional description: Thinning, lightening or darkening of skin at injection site | | |
| subjects affected / exposed | 4 / 116 (3.45%) | 0 / 118 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | Additional description: For steroid injection, hand or wrist was more painful following injection. For splinting, participants unable to wear splint because of discomfort. | | |

| | | | |
|-----------------------------|-------------------|-----------------|--|
| subjects affected / exposed | 53 / 116 (45.69%) | 7 / 118 (5.93%) | |
| occurrences (all) | 53 | 7 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 03 July 2013 | Addition of questions concerning baseline characteristics, prognostic factors, employment, and effect of previous treatments to participant questionnaires. Changes to consent form, participant information leaflet. |
| 12 September 2013 | Change to protocol, participant information leaflet and consent form detailing hosting of the trial database on the University of Birmingham secure server. |
| 07 November 2014 | Change to protocol, participant information leaflet and consent form detailing moving trial database to Keele University secure server. Addition of question concerning laterality of symptoms to baseline questionnaire. |
| 19 March 2015 | Addition of two questions about undergoing surgery for hand/wrist problems to minimum data collection questionnaires. |
| 21 May 2015 | Clarification within protocol of the original intention with regard to processes relating to supply and administration of trial IMP under a patient group directive by specified authorised healthcare professionals. |
| 08 August 2016 | Change of Chief Investigator |
| 18 January 2018 | Clarification of reporting processes for deaths, non-fatal SAEs and pregnancies after 6-week follow-up. |
| 03 September 2018 | Update to Summary of Product Characteristics for methylprednisolone acetate. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Trial participants and clinicians were not masked to treatment allocation. We recruited two short of the target 240 participants; however, statistical power was retained because of higher than anticipated follow-up rates.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/27716159>

<http://www.ncbi.nlm.nih.gov/pubmed/30343858>