

Trial Description

Title

Manual therapy intervention for carpal tunnel syndrom - a pilot study

Trial Acronym

Man-CTS

URL of the trial

[---]*

Brief Summary in Lay Language

Does a manual therapy intervention of the wrist improve clinical symptoms and electrophysiological results in patients with carpal tunnel syndrom?
Patients with clinical and elektrophysiologisch diagnosed carpal tunnel syndrom receive either manual therapy intervention of the wrist or care as usual in randomized order.

Follow up over 6 month consists of standardized questionnaire (Boston Carpal Tunnel Questionnaire) and electrophysiologic conduction studies.

Brief Summary in Scientific Language

Randomized controlled study comparing manual chiropractic with usual care in patients with clinical and electrophysiologic confirmed carpal tunnel syndrom (CTS):

40 consecutively recruited patients with confirmed CTS (electric conduction study). Patients will be recruited in a specialist practice

Intervention:

Chiropractic manipulation of the wrist

Control: No intervention (care as usual)

Inclusion criteria:

Clinical and electrophysiologic confirmed CTS

Exclusion criteria:

Patient not willing or able to participate.

Wrist fracture, acute infection/wound of the wrist/hand.

Indication for surgery

Outcome:

o Severity and functional status (severity symptom score, functional status score) according to Boston Carpal Tunnel Questionnaire (primary outcome)

o Comparison of further therapies used between control and intervention group (secondary outcome)

o Feasibility of an intervention study with chiropractic manipulation

Follow up:

T1: after 2 weeks (Questionnaire)



T2: after 3 month (Questionnaire, electrophysiologic conduction studies)

T3: after 6 month (Questionnaire)

Organizational Data

- DRKS-ID: **DRKS00000567**
- Date of Registration in DRKS: **2010/10/05**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **5517 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- ICD10: **G56.0 - Carpal tunnel syndrome**
- ICD10: [---]* - [---]*

Interventions/Observational Groups

- Arm 1: **manual therapy intervention of the wrist**
- Arm 2: **Care as usual**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Study Type: **Interventional**

Study Type Non-Interventional: [---]*

Allocation: **Randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

Control: **Other**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Symptom severity and functional status according to the scores from Boston Carpal Tunnel Questionnaire were assessed after 2 weeks, 3 and 6 month by postal questionnaire

Secondary Outcome

Outcome:

- **Descriptive comparison of further therapies used between control and intervention group (secondary outcome) will be assessed after 2 weeks, 3 and 6 month using standardized questionnaires**
- **Feasibility of an intervention study with chiropractic manipulation (response rate, drop out, lost to follow up)**
- **Clinical status and nerve conduction studies will be repeated after 3 month**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- **Planned/Actual: Actual**



Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2010/11/16**

- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

Patients with clinically suspected diagnosis of carpal tunnel syndrom confirmed by nerve conduction studies

Exclusion criteria

Exclusion criteria:

Patient not willing or able to participate.

Wrist fracture, acute infection/wound of the wrist/hand.

Indication for surgery

Addresses

■ Primary Sponsor

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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/11/02**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.