

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**Manual Mobilization of the thoracic spine: Effect on pain free grip and sympathetic nervous system activity on patients with lateral epicondylitis humeri**

### Trial Acronym

**MT BWS Epicondylitis**

### URL of the trial

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### Brief Summary in Lay Language

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### Brief Summary in Scientific Language

**Lateral epicondylitis humeri (tennis elbow) is among the most common musculoskeletal disorders in the working population between 35 and 55 of age. The first choice to treat a tennis elbow is conservative therapy and a variety of conservative treatment strategies seem effective. There is a clue that, besides treatment directly applied to the elbow, spinal manual therapy is also effective in the management of lateral epicondylitis.**

**Aim of this study is to check if spinal manual therapy applied to the thoracic spine reduces pain in patients with tennis elbow.**

**Patients (male and female) with unilateral epicondylitis lateralis humeri age between 18 and 55 years and clinically diagnosed epicondylitis lateralis humeri are included in this trial.**

**Eligible patients are informed about the procedure and sign the informed consent form and are randomized in two groups.**

**The Patients perform a pain free grip test, which is a common, reliable and valid test for tennis elbow. The test is performed on the affected and non-affected side, in a supine position, arms next to the body, elbow extended and a prone hand.**

**Patients are instructed to squeeze as strong as possible on the non-affected side and only until pain occurred on the affected side. T5/6 joint is identified by counting downwards from vertebra prominens and labeled. Subjects are placed in a prone position, cervical spine neutral, arms next to the body, palms up.**

**Fingertips and sensors are cleaned with a disinfectant containing 73,5% ethanol. Then Skin conductance sensors are placed on the palmar surface of the index and ring finger, skin temperature sensor was fixed palmar surface of the middle finger. Subjects undergo a 20 mins stabilization period followed by either the mobilization or placebo for two minutes. Pain free grip is tested, using the same protocol as pre intervention.**

**Hypothesis:**

**Spinal Manual Therapy, applied to the thoracic spine increases pain free grip on the affected side on patients with lateral epicondylitis. Additionally skin conductance increases and peripheral skin temperature decreases in the mobilization group.**

**Aim of the study:**

**Development of a treatment strategy aside the symptomatic area for patients with lateral epicondylitis. So far, sympathoexcitation and reduction of pain following Spinal Manual Therapy has been almost exclusively shown in an asymptomatic population but not in a symptomatic one. There are some studies that indicate that there is sympathoexcitation after a cervical mobilization and only a couple of studies for thoracic mobilizations.**

## Organizational Data

- DRKS-ID: **DRKS00013964**
- Date of Registration in DRKS: **2018/02/02**
- 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.: **415-E/2158/4-2017 , Ethikkommission für das Land Salzburg / Österreich**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **M77.1 - Lateral epicondylitis**

## Interventions/Observational Groups

- Arm 1: **Intervention Group: 2 min Manual Mobilisation of the costo-transversal joint (T5/6) on the affected side with 2 Hz**
- Arm 2: **Placebo Group: 2 min sham-ultrasound therapy on the costa-transversal joint (T5/6) on the affected side**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
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Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: [---]\*

- Who is blinded: **patient/subject, data analyst**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Painfree grip measured with a calibrated hand dynamometer (KERN MAP 80K1S). Measurement pre and post intervention.**

### Secondary Outcome

**Skin conductance and skintemperatur are measured with a MindMedia Nexus-4 biofeedback device (Software: BioTrace V2015B1). Measurement pre and post intervention.**

### Countries of recruitment

- AT **Austria**

### Locations of Recruitment

- Medical Center **Universitätsklinik für Orthopädie und Traumatologie, Salzburg**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/05/16**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **55 Years**

### Additional Inclusion Criteria

**Patients with clinically diagnosed lateral epicondylitis humeri**

### Exclusion criteria

**bilateral elbow pain, osteoporosis, tumor diseases, history of operations on the elbow or tho-racic spine, acute thoracic pain, pregnancy, oral anticoagulation, central pain medication, bi-ased to manual therapy**  
Exclusion criteria were predefined and retrieved in patients' case histories.

### Addresses

#### ■ Primary Sponsor

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#### ■ Collaborator, Other Address

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## Sources of Monetary or Material Support

#### ■ Institutional budget, no external funding (budget of sponsor/PI)

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## Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2018/01/16**

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Deutsches Register  
Klinischer Studien

German Clinical  
Trials Register

## Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**
- trial protocol (mandatory for transfer to Studybox) **Prüfprotokoll**

\* *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.*