



## Trial Description

### Title

**Musculoskeletal dysfunctions in patients with migraine or tension-type headaches**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**It is unclear whether problems in the cervical spine or neck muscles contribute to migraine or tension-type headaches. We are investigating whether there is a difference regarding such problems between patients suffering from headaches and persons without headaches.**

### Brief Summary in Scientific Language

**There is an ongoing scientific debate about the contribution of neuromusculoskeletal dysfunctions to headache syndromes. This study will investigate differences in musculoskeletal dysfunctions between patients with migraine or TTH and headache-free control participants using a blinded protocol.**

## Organizational Data

- DRKS-ID: **DRKS00009622**
- Date of Registration in DRKS: **2015/11/06**
- 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.: **PV5011 , Ethik-Kommission der Ärztekammer Hamburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **G43 - Migraine**
- ICD10: **G44.2 - Tension-type headache**

## Interventions/Observational Groups

- Arm 1: **Physiotherapy examination of patients with migraine or TTH**
- Arm 2: **Physiotherapy examination of healthy control participants**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: [---]\*
- Who is blinded: **investigator/therapist**
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

### Cluster of tests identified in an international consensus procedure:

- head forward posture
- range of cervical movement
- range of thoracic movement
- upper cervical quadrant
- passive physiological cervical movements
- flexion-rotation test
- manual joint examination cervical spine and thoracic spine
- trigger point palpation
- cranio-cervical flexion test

## Secondary Outcome

### Questionnaires:

- MIDAS (migraine associated disability)
- Neck Disability Index
- PHQ9 (depression)
- personal data: age, gender, headache history, headache frequency, duration, intensity, sports, BMI



## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Hamburg**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/04**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

## Additional Inclusion Criteria

**Diagnosed with migraine or TTH by headache expert**

## Exclusion criteria

**diagnosed pathology of the neck; neck pathology in the past 2 years; diagnosed psychiatric, rheumatoid or other neurological disease**

## Addresses

- **Primary Sponsor**

**Universitätsklinikum Hamburg-Eppendorf  
Martinistr. 52  
20246 Hamburg  
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#### ■ **Contact for Scientific Queries**

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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): **2017/12/31**

## 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.