

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

## Trial Description

### Title

**Predicting the outcome of conservative treatment with physiotherapy for shoulder pain in the presence of atraumatic partial-thickness tears of the rotator cuff**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The primary aim of this study is to investigate potential factors that may predict the outcome of conservative treatment with physiotherapy for patients with shoulder pain and degenerative partial-thickness rotator cuff tears as diagnosed by ultrasonography.**

**The rotator cuff, a deep cuff of four tendons around the shoulder, is often involved in a degenerative process that may culminate in tears. These tears may be partial-thickness or full-thickness. Rotator cuff tears can significantly affect shoulder function and quality of life. The precise indications for different treatment approaches for patients with shoulder-pain and partial-thickness rotator cuff tears are yet unclear: whereas some patients respond very well to conservative treatment including physiotherapy, others respond less well, or respond to surgical treatment. Early identification of likely responders and, by corollary, non-responders to a defined treatment approach could save unnecessary effort and suffering and could help to find the best treatment for the individual patient.**

**This study is an observational study, meaning that we just follow the conservative treatment that is usually recommended to patients with shoulder pain and partial-thickness rotator cuff tears. We expect to find out about a set of factors that are likely to predict response to treatment.**

### Brief Summary in Scientific Language

**The primary aim of this study is to develop a predictive model for the outcome of conservative treatment with physiotherapy for patients with shoulder pain and ultrasonographically diagnosed atraumatic partial-thickness rotator cuff tears.**

**The rotator cuff, a deep cuff of four tendons around the shoulder, is often involved in a degenerative continuum culminating in tears. These tears may be partial-thickness or full-thickness. Rotator cuff tears can significantly affect shoulder**

**function and quality of life. The available research reflects the current uncertainty as to precise indications for different treatment approaches: some patients with PTTs respond well to conservative treatment including physiotherapy, while others respond less well, or respond to surgical treatment. Early identification of likely responders and, by corollary, non-responders to a defined treatment approach could save effort and suffering and could promote the optimal distribution of available resources.**

**This study is a non-interventional prognostic cohort study. We aim to generate a hypothesis and determine a predictive model that represents a set of likely predictors of response to treatment.**

## Organizational Data

- DRKS-ID: **DRKS00004462**
- Date of Registration in DRKS: **2014/04/08**
- 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.: **PV4154 , Ethik-Kommission der Ärztekammer Hamburg**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1155-3740**

## Health condition or Problem studied

- ICD10: **M75.1 - Rotator cuff syndrome**

## Interventions/Observational Groups

- Arm 1: **Patients are observed over a three-month period of conservative treatment including physiotherapy (with or without adjunctive medical treatment, e.g. analgetics, injections).**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*



Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Single arm study**

Blinding: [---]\*

Who is blinded: [---]\*

- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Patient-reported Health-related Quality of Life (HrQoL)/disability as measured through the validated German version of the Western Ontario Rotator Cuff Index (WORC; Huber et al. 2005); assessment: end of observation period (regular follow-up assessment).**

### Secondary Outcome

- **Patient-reported perception of perceived change as measured by a Likert-type "Global perceived change" scale**
- **Progression of the rotator cuff tear from partial to full-thickness as assessed by ultrasonography; assessment: end of observation period.**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- Doctor's Practice **Hamburg**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/05**
- Target Sample Size: **152**
- Monocenter/Multicenter trial: **Monocenter trial**



Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2012/12/05**

Target Sample Size: **152**

Monocenter/Multicenter trial: **Monocenter trial**

■ National/International: **National**

### Inclusion Criteria

■ Gender: **Both, male and female**

■ Minimum Age: **18 Years**

■ Maximum Age: **no maximum age**

### Additional Inclusion Criteria

#### Inclusion:

• **Patients with (local) shoulder pain in the presence of an atraumatic**

**(ultrasonographically detected) partial thickness rotator cuff tear (PTT)**

### Exclusion criteria

#### Exclusion:

(e.g. cancer, cardiac insufficiencies)

## Addresses

### ■ Primary Sponsor

**Teesside University, School of Health and Social Care**

**Mr. Prof Paul Keane, Dean, als verantwortliche/betreuende Institution des PhD von C. Braun (s.u., Studie ist Teil eines PhD (keine finanzielle Förderung)); as responsible/supervising institution of C. Braun's PhD (study is part of a PhD programme (see below, no financial funding))**

**Centuria Building**

**TS1 3BA Middlesbrough**

**United Kingdom**

Telephone: [---]\*

Fax: [---]\*

E-mail: **sohscadmissions at tees.ac.uk**

URL: **http://www.tees.ac.uk/schools/soh/**

### ■ Contact for Scientific Queries

**Schulter-Zentrum.com**

**Mr. Dr. med. Andreas Betthäuser**

**c/o Ev. Krankenhaus Alsterdorf**

**22337 Hamburg**

**Germany**

Telephone: **04046073550**

Fax: [---]\*

E-mail: **info at schulter-zentrum.com**

URL: **http://schulter-zentrum.com/**

### ■ Contact for Public Queries

**Schulter-Zentrum.com**

**Mr. Dr. med. Andreas Betthäuser**

**c/o Ev. Krankenhaus Alsterdorf**

**22337 Hamburg**

**Germany**

Telephone: **040 460 735 50**

Fax: [---]\*

E-mail: **info at schulter-zentrum.com**

URL: **http://schulter-zentrum.com/**

### ■ Contact for Public Queries



### Contact for Public Queries

**Korrespondenzadresse: c/o Dr. med. Andreas Betthäuser, Schulter-Zentrum.com, Ev. Krankenhaus Alsterdorf**

**Ms. Cordula Braun**

**Elisabeth-Flügge-Str. 1**

**22337 Hamburg**

**Germany**

Telephone: **(0049) 0176 999 628 68**

Fax: [---]\*

E-mail: **C.Braun at tees.ac.uk**

URL: [---]\*

### Sources of Monetary or Material Support

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

**Schulter-Zentrum.com**

**Mr. Dr. med. Andreas Betthäuser**

**c/o Ev. Krankenhaus Alsterdorf**

**22337 Hamburg**

**Germany**

Telephone: **040 460 735 50**

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

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

**Kontaktadresse D: hochschule 21**

**Ms. Cordula Braun**

**Harburger Str. 6**

**22146 Buxtehude**

**Germany**

Telephone: **(0049) 0176 999 628 68**

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### Status

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

■ Study Closing (LPLV): **2015/01/16**

DRKS-ID: **DRKS00004462**

Date of Registration in DRKS: **2014/04/08**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

## Trial Publications, Results and other documents

- Paper **Braun et al. 2018, Studienbericht, BMC Musculoskeletal Disorders**
- Paper <style fontName='DejaVu Sans' isBold='true'>Braun & Handoll 2018 Bericht MID-Analyse, Musculoskeletal Science and Practice</style>

\* 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.