

# Integration of the traditional Chinese medicine into the orthopedic rehabilitation - effects on pain and employment prognosis for patients with chronic back pain

<b>Submission date</b> 05/07/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/07/2006	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.refonet.de>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

04003

## **Study information**

**Scientific Title**

### **Study objectives**

By additional therapy elements of Traditional Chinese Medicine (TCM) within an orthopedic rehabilitation procedure over four weeks with chronic back pain inpatients, a higher reduction of pain and analgesic consumption can be achieved, as well as a decrease in the amount of times there is an inability to work and improvement of the subjective employment prognosis.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of the Physicians Chamber, Rheinland-Pfalz, Mainz on 17/11/2005 (reference number 837.258.05).

### **Study design**

Prospective, randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Chronic back pain

### **Interventions**

The patients of group A are treated exclusively according to schooled medical therapy concept for four weeks. The patients of group B are treated with elements of the TCM additionally. These contain acupuncture and tuina- massage twice in each case per week

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Traditional Chinese medicine

**Primary outcome measure**

1. Reduction of the pain
2. Reduction of the analgesic consumption

**Secondary outcome measures**

1. Decrease in the amount of times there is an inability to work
2. Improvement of the subjective employment prognosis

**Overall study start date**

01/01/2006

**Completion date**

30/06/2008

**Eligibility****Key inclusion criteria**

1. Aged 30 to 55 years
2. Able to gain employment
3. Chronic back pain
4. Medication: not opioid analgesics (World Health Organisation stage I)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

270 participants (135 group A, 135 group B)

**Key exclusion criteria**

1. Acute slipped disk in the last three months
2. Pension required
3. Spinal column operation in the past

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

30/06/2008

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Orthopedic Rehabilitation Center

Bad Ems

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**Sponsor information****Organisation**

Refonet (Germany)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.refonet.de>

**ROR**

<https://ror.org/04yeh2x21>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Refonet, project no. 04003

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration