# Effectiveness of a general neck exercise program, of acupuncture or of repetitive low-energy shockwave therapy for chronic neck disorders

Submission date	Recruitment status	[X] Prospectively registered
14/12/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
04/01/2010	Completed	Results
Last Edited	Condition category	Individual participant data
04/01/2010	Musculoskeletal Diseases	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Jan D Rompe

#### Contact details

OrthoTrauma Evaluation Center Mainz Germany 55130

# Additional identifiers

Protocol serial number

N/A

# Study information

## Scientific Title

Treatment of neck disorders with exercises, acupuncture or shockwave therapy: a randomised controlled trial

## Study objectives

Null hypothesis:

A general neck exercise program, acupuncture and shockwave therapy produce equivalent outcomes at 4 months from baseline.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Neck disorders

### **Interventions**

General neck exercise program:

Posture correction techniques and active range of movement exercises are delivered. The active range of movement exercises prescribed are at the therapist's discretion, but can include flexion, extension, side flexion, and rotation. Posture correction will be taught in the context of functional and work activities.

Total duration of treatment: 4 weeks

Total duration of follow-up: 15 months from baseline

## Acupuncture:

We use single-use, sterile, silver-handle, prepacked needles without guide tubes. We base point selection on individualised western acupuncture techniques by using a list of points previously reported as being effective in neck pain. The specific points for each individual are defined at each treatment session, depending on the patient's pain distribution and palpation of the neck and thorax to determine ah-shi points, or local tender points, for acupuncture. At least 1 distal point is used.

Total duration of treatment: 4 weeks

Total duration of follow-up: 15 months from baseline

## Shockwave therapy:

Painful muscles are identified and tender points are treated with low-energy shockwave therapy (EFD = 0.1 mJ/mm<sup>2</sup>, 2000 shocks per muscle, 3 sessions 1 - 2 weeks apart).

Total duration of treatment: 4 weeks

Total duration of follow-up: 15 months from baseline

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome(s)

- 1. Neck pain on a 100 mm visual analogue scale
- 2. Disability assessed with the 100 point neck disability index

Measured at 2 months, 4 months and 15 months from baseline.

## Key secondary outcome(s))

Treatment satisfaction, assessed on a five point scale: 1 = very satisfied, 2 = satisfied, 3 = equivocal, 4 = unsatisfied, and 5 = very unsatisfied; Scores of 1 and 2 are classified as "satisfied" and scores of 4 and 5 as "unsatisfied.

Measured at 2 months, 4 months and 15 months from baseline.

## Completion date

31/12/2012

# **Eligibility**

## Key inclusion criteria

- 1. Aged 18 years and older, either sex
- 2. Neck pain symptoms for longer than 3 months
- 3. Referred to therapy with a new episode of neck pain by their general practitioner (GP). Non-specific neck pain is defined as pain and/or stiffness in the cervical spine, with or without unilateral arm pain, after the exclusion of red flags.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

- 1. Weight loss
- 2. Fever
- 3. Progressive neurological signs including bilateral arm pain
- 4. Evidence of muscle weakness or disturbance in normal sensation
- 5. History of malignancy, inflammatory arthritis, polymyalgia rheumatica, osteoporosis, or gross structural or neurologic abnormality affecting the neck

- 6. Contraindications to the study treatments (e.g., patients taking anticoagulants)
- 7. Any injury awaiting a compensation claim (e.g., deceleration or industrial injury)
- 8. Pregnancy

## Date of first enrolment

01/03/2010

## Date of final enrolment

31/12/2012

## Locations

## Countries of recruitment

Germany

Luxembourg

Study participating centre
OrthoTrauma Evaluation Center

Mainz Germany 55130

# **Sponsor information**

## Organisation

German and International Society for Extracorporeal Shock Wave Therapy (DIGEST) (Germany)

# Funder(s)

## Funder type

Research organisation

## **Funder Name**

German and International Society for Extracorporeal Shock Wave Therapy (Deutsche und Internationale Gesellschaft für Extrakorporale Stoßwellentherapie [DIGEST]) (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes