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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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^2, 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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/03/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350

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)

Sponsor details
Kurfürstendamm 61
Berlin
Germany
10707

Sponsor type
Research organisation

Website
http://www.digest-ev.de

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

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