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Acupuncture at local and distal points for chronic shoulder pain

Submission date
19/11/2013

Recruitment status
No longer recruiting

Registration date
23/12/2013

Overall study status
Completed

Last Edited
22/04/2014

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic shoulder pain (CSP) is the third most common type of musculoskeletal pain, and can have a major impact on health-related quality of life. Disorders of the shoulder muscles and tendons (strong bands or cords of tissue that attach muscle to bone) are thought to be the most common cause of the pain. The true prevalence is unknown, varying in different reports from 4-34%. The common treatments for shoulder pain are nonsteroidal anti-inflammatory drugs (NSAIDs), physiotherapy, cortisone injections and wait and see. Unfortunately, none of these treatments is clearly proven to be effective for CSP in the long run. In Chinese Medicine, chronic shoulder pain is considered one of the indications that respond well to treatment with acupuncture. The purpose of this study is to evaluate whether local acupoints (acupoints are any of the supposed energy points on the body where acupuncture needles are inserted) in combination with distal acupoints are more effective than local acupoints or distal acupoints alone in reducing pain and improving shoulder function in people with CSP.

Who can participate?
Participants diagnosed with chronic shoulder pain.

What does the study involve?
Participants are randomly allocated to one of four groups:
Group A (receive acupuncture at local acupoints in combination with distal acupoints)
Group B (receive acupuncture at local acupoints in combination with distal non-acupoints)
Group C (receive acupuncture at local non-acupoints in combination with distal acupoints)
Group D (receive acupuncture at local non-acupoints in combination with distal non-acupoints).
Participants are asked to come twice a week for 40 minutes acupuncture treatment. Treatment is expected to have been completed by 6 weeks but further questionnaires will be asked at 6, 10 and 18 weeks later after first acupuncture session. Each acupuncture session lasts about 30 minutes.

What are the possible benefits and risks of participating?
It is expected that participants will experience decrease in pain and improved function and strength. Furthermore, the information that is gained from this study will help inform future research.

The risks of taking part are minimal. Acupuncture is a very safe treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or experience a temporary increase in pain either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?
The study is run from Huairou District Hospital of Traditional Chinese Medicine, Beijing, China, Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, China and Dongzhimen Hospital of Traditional Chinese Medicine of Beijing University, China.

When is the study starting and how long is it expected to run for?
The study is expected to start in January 2014 and will run until December 2015.

Who is funding the study?
Beijing Bureau of Medical Science and Technology project funding (China)

Who is the main contact?
Dr Cun-Zhi Liu
lcz623780@126.com

Contact information

Type(s)
Scientific

Contact name
Dr Cun-Zhi Liu

Contact details
23 Meishuguanhou Street
Dongcheng District
Beijing
China
100010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011-3-055

Study information

Scientific Title

Acupuncture at local and distal points for chronic shoulder pain: multi-center, factorial randomized controlled clinical trial

Study objectives
To evaluate the efficacy of acupuncture at local points in combination with distal points in chronic shoulder pain patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 22/03/2013, ref: 201315

Study design
Block randomized single blind 2×2 factorial design

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
Chronic shoulder pain

Interventions
Participants will receive acupuncture at local points in combination with distal points for 6 weeks.
Time points are as follows:
Visit 1: screening
Visit 2: treatment initiation, participants will receive acupuncture for 6 weeks
Visit 3: 6 weeks after first acupuncture, treatment finish and follow-up
Visit 4: 10 weeks after first acupuncture, follow-up
Visit 5: 18 weeks after first acupuncture, follow-up

Patients who meet the inclusion criteria are randomized to one of four treatment groups:
Group A will receive acupuncture at local acupoints in combination with distal acupoints.
Group B will receive acupuncture at local acupoints in combination with distal non-acupoints.

Group C will receive acupuncture at local non-acupoints in combination with distal acupoints. Group D will receive acupuncture at local non-acupoints in combination with distal non-acupoints.

Local acupoints:
Jianyu (large Intestine meridian [LI] 15)
Jianliao (triple energizer meridian [TE] 14)
Jianzhen (small intestine meridian [SI] 9)
Tiaokou (stomach meridian 38)

Local non-acupoints:
Local non-acupoint 1: anterior axillary fold
Local non-acupoint 2: posterior axillary fold
Local non-acupoint 3: In the shoulder department, 2cm below Tianzong (scapula) (SI 11)
Local non-acupoint 4: Inside of the upper arm side, Tianfu (lung meridian 3) inward 1 cm, midpoint between pericardium meridian and lung meridian

Distal non-acupoint:
Distal point 1: lateral to the shank, 3cm below Yanglingquan (gallbladder meridian 34), the midway between gallbladder meridan and bladder meridian

Treatment will be conducted over a period of 6 weeks, at a frequency of 2 sessions/week.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Shoulder pain intensity is graded using Visual Analogue Scale (VAS). The assessment is at baseline (before treatment initiation), 6 weeks later of the first acupuncture, 10 weeks after first acupuncture and 18 weeks after first acupuncture.

Secondary outcome measures
1. Functions of the shoulder joint are evaluated by Constant-Murley score (CMS). The assessment is at baseline (before treatment initiation), 6 weeks after first acupuncture, 10 weeks after first acupuncture, and 18 weeks after first acupuncture.
2. Quality of life is assessed by Short form-36 (SF-36). The assessment is at baseline (before treatment initiation), 6 weeks after first acupuncture, 10 weeks after first acupuncture, and 18 weeks after first acupuncture.
3. Perceived Credibility of acupuncture is evaluated by The Treatment Credibility Scale (TCS) after a 6-week acupuncture session. It is a 5-item questionnaire ranging from 1 (not at all) to 5 (very confident); items are averaged to provide a single treatment credibility score, with high scores reflecting high treatment credibility.
4. Participants also report adverse events they experience, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after a 6-week acupuncture session.

Overall study start date
01/01/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Age between 25 and 65 years, either sex
2. Primary complaint of shoulder pain with one-sided shoulder pain for at least 6 weeks and up to 2 years
3. A pain score of 50 mm or more on a 100-mm visual analogue scale (VAS)
4. Plain radiography is normal, but may have osteoporosis or calcification shadow
5. Individuals who have not received acupuncture in the preceding 1 month
6. Signed informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
164

Key exclusion criteria
1. Referred pain from the cervical spine, history of shoulder trauma, shoulder surgery, stroke, ipsilateral breast surgery, heart diseases and severe hypertension
2. Osteoarthritis of the gleno-humeral joint or systemic bone and joint disorder (e.g. rheumatoid arthritis)
3. Endocrine diseases such as hyperthyroidism
4. Severe infection
5. Current therapy involving analgesics

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
China

Study participating centre

23 Meishuguanhou Street
Beijing
China
100010

Sponsor information

Organisation
Beijing Municipal Health Bureau (China)

Sponsor details
70 Zaolinqian Sreet, Xuanwu District
Beijing
China
100053

Sponsor type
Government

ROR
https://ror.org/0374a5s68

Funder(s)

Funder type
Government

Funder Name
Beijing Health System (China) - High Level Health Technology Talent Cultivation Plan ref: 2011-3-055

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/04/2014		Yes	No