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Shoulder pain: To needle or not to needle? The role of acupuncture in the treatment of shoulder pain

Submission date
17/07/2015

Recruitment status
No longer recruiting

Registration date
27/07/2015

Overall study status
Completed

Last Edited
13/12/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Musculoskeletal disorders of the shoulder are extremely common, with 1 in 3 people experiencing shoulder pain at some stage of their lives. As the shoulder is used to place the hand, problems in this part of the body have a negative impact on daily living (personal hygiene, dressing, eating and work). The experience of pain is the most common complaint for patients with shoulder problems and the presence of pain leads to a significant reduction in shoulder strength (pain inhibition), a loss of sensory motor control (proprioception) and functional impairment.
The main treatments are advice and exercise and there is evidence that these work well. Healthcare professionals have also started using acupuncture, which involves the use of sterile single-use dry needles inserted at specific locations. The use of electro-acupuncture has been recommended to enhance the effect of the acupuncture needles, which involves electrical stimulation of the inserted needles similar to transcutaneous electric nerve stimulation (TENS) which is used widely in pain management programmes. However there is little evidence that electro-acupuncture works well for shoulder pain and the aim of this study is to compare no acunpuncture vs acupuncture vs electro-acupuncture.

Who can participate?
Adult patients with chronic (>3 months) shoulder pain.

What does the study involve?
Potential participants will have at least one week to decide if they wish to participate and during this time they will be encouraged to discuss their participation with family, friends, the principal investigator and other relevant healthcare professionals. This is because there is a waiting period from the time a referral is brought to the physiotherapy department and when an available first treatment time is available. Potential participants will be made aware that the waiting time to start treatment will be the same for those participating and not participating in the study.
Actual participants will be randomly (using thick, non-transparent envelopes kept in a locked office) allocated to one of three groups:

Group I: Shoulder advice and exercise group (6, approximately 60 minute sessions).
Group II: Shoulder advice and exercise group (6, approximately 60 minute sessions) together with 6 treatments of acupuncture (twice a week for the first 3 weeks of the 6 week programme).
Group III: Shoulder advice and exercise group (6, approximately 60 minute sessions) together with 6 treatments of electro-acupuncture (twice a week for the first 3 weeks of the 6 week programme.
Measurements will be taken before the commencement of the study, immediately after, at 6 months and 12 months.

What are the possible benefits and risks of participating?
We do not currently know the most effective treatments for shoulder pain and we hope that this research will help us understand the best way to treat this problem. However, as with all research, this cannot be guaranteed.
There are no perceived disadvantages or risks for those taking part in this study. The examination procedures and treatment procedures are ones used daily in physiotherapy clinics. Although acupuncture needles are very fine, some people find the needles to cause mild discomfort. This is substantially much less than a normal injection. Acupuncture is generally very safe. Serious side effects are very rare occurring in less than one in 50,000 treatments. There are some side affects you need to be aware of: drowsiness can occur following treatment in a small number of patients and if you are affected you are advised not to drive.
Minor bleeding or bruising occurs after treatment in about 3% of treatments. Pain during treatment occurs in about 1% of treatments. Existing symptoms may get worse after treatment in less than 3% of patients. Feeling light headed or fainting may occur in certain patients, particularly at the first treatment. Some people find the shoulder tests we perform produce some pain. In most cases this will be similar to the pain you are experiencing in your shoulder. The tests are used to determine which structure or structures are involved with your pain. We also perform these tests to see if you are improving as a result of the treatment you have received.

Where is the study run from?
4 sites in the UK: Chelsea and Westminster Hospital, Ipswich Hospital NHS Trust, Royal Bournemouth and Christchurch NHS Trust, Warrington PCT NHS Trust

When is the study starting and how long is it expected to run for?
January 2007 to May 2013

Who is funding the study?
Westminster Medical School Research Trust (UK)

Who is the main contact?
Dr Jeremy Lewis

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Lewis

Contact details

Department of Allied Health Professions and Midwifery
School of Health and Social Work
Wright Building
College Lane Campus
University of Hertfordshire
Hatfield
United Kingdom
AL10 9AB

Additional identifiers

Protocol serial number
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Study information

Scientific Title
A multicentre randomised trial comparing exercise, acupuncture and electro-acupuncture for people with shoulder pain

Study objectives
Null hypothesis: there will be no difference between the 3 groups (1) exercise, (2) exercise and acupuncture, and (3) exercise and electro-acupuncture in the treatment of people experiencing shoulder pain of a musculoskeletal origin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Riverside Research Ethics Committee Charing Cross Hospital, 21/01/2007, REC reference: RREC 07/Q0401/2

Study design
Randomised clinical trial (multi-site)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shoulder pain of musculoskeletal origin

Interventions
Group 1: Shoulder exercise group
Group 2: Shoulder exercise group and acupuncture
Group 3: Shoulder exercise group and electro-acupuncture

Intervention Type

Other

Primary outcome(s)
1. Oxford Shoulder Score (a validated 12 question questionnaire which requires tick box responses relating to the patients symptoms and level of disability)

Outcome measurements will be taken (1) before the commencement of the programme, (2) immediately after the programme, (3) at 6 months and (4) at 12 months.

Key secondary outcome(s))
1. Shoulder Pain and Disability Index (SPADI), another validated shoulder questionnaire which also includes Visual Analogue Scales for pain
2. Shoulder range of movement (shoulder flexion, abduction, external rotation and internal rotation) measured with goniometers and tape measurer
3. Shoulder strength measured with a validated shoulder strength testing dynanometer.
4. Global impression of change

Outcome measurements will be taken (1) before the commencement of the programme, (2) immediately after the programme, (3) at 6 months and (4) at 12 months.

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Patients referred to physiotherapy departments who have pain in the region of their shoulder
2. Minimum duration of symptoms being 3 months
2. Being able fully communicate in English
3. A minimum age of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pain referred from the cervical spine
2. A history of shoulder instability, subluxations, dislocations
3. Un-united fractures involving the shoulder

4. Malunion or non-union of fractures
5. Inability to participate in an exercise programme
6. Systemic diseases such as rheumatoid arthritis, diabetes, uncontrolled blood pressure, cardiac disease, renal insufficiency, cardiac pacemakers, hearing aids
7. Women who are pregnant, attempting to become pregnant
8. Fear of needles (participants may be randomised to a group where acupuncture needles will be used).
9. Infections (systemic or local)
10. Fragile, swollen, thin or inflamed skin
11. Post-surgical lymphoedema
12. Known allergy to metals
13. Recent oral steroid therapy or shoulder injections
14. Epilepsy
15. Patients on anti-coagulation therapy
16. Patients with Hemophilia

Date of first enrolment
31/07/2007

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
United Kingdom

Study participating centre
Chelsea and Westminster Hospital
Physiotherapy Department
London
SW10 9NH

Study participating centre
The Ipswich Hospital NHS Trust
Physiotherapy Department
IP4 5PD

Study participating centre
Royal Bournemouth and Christchurch NHS Trust
Physiotherapy Department
BH7 7DW

Study participating centre
Warrington PCT NHS Trust
Physiotherapy Department
WA2 7NE

Sponsor information

Organisation
Chelsea and Westminster Hospital

ROR
https://ror.org/038zxea36

Funder(s)

Funder type
University/education

Funder Name
Westminster Medical School Research Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes