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The efficacy of pulsed radiofrequency on chronic shoulder pain

Submission date
20/11/2012

Recruitment status
No longer recruiting

Registration date
22/03/2013

Overall study status
Completed

Last Edited
21/10/2016

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
There are many treatments for chronic (long-term) shoulder pain, including physiotherapy, painkillers and corticosteroid (hormone) injections. However, there is limited evidence of their effectiveness. Often surgery is not an option for patients who have multiple other illnesses or are unwilling to undergo surgery. Pulsed radiofrequency is a new method for treating shoulder pain. It involves using a needle to apply an electrical field to the nerve which may be responsible for transmitting pain signals to the brain. The aim of this study is to assess the effectiveness of pulsed radiofrequency for chronic shoulder pain.

Who can participate?
Patients aged over 20 with chronic shoulder pain

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives an injection of local anesthetic and undergoes PRF treatment for 3 minutes (two cycles). The other group receives an injection of local anesthetic. Shoulder pain and range of motion are assessed in both groups at the start of the study and after 1 week, 3 months and 6 months.

What are the possible benefits and risks of participating?
Participants may benefit from pain relief for a couple of months. The possible risks include subcutaneous hematoma (bruise), infection, pain during treatment, and allergy.

Where is the study run from?
E-Da Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2011 to December 2012

Who is funding the study?
I-Shou University (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pulsed radiofrequency lesioning for painful shoulder: a prospective, randomized, single-blinded study

Study objectives
The efficacy of pulsed radiofrequency lesioning on suprascapular nerve is better than placebo group (lidocaine injection only) in patients with chronic shoulder pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
E-Da Hospital, January 2011, ref: EMRP37098N

Study design
Randomised single-blind single-centre placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic shoulder pain

Interventions
Each patient is placed in a prone position, and the skin overlying the peration area was prepared and draped. A standard radiofrequency lesion generator (Neurotherm JK 25T) was used for the whole procedure. The suprascapular notch was identified under C-arm fluoroscopy at an angle slightly oblique to the treated side and angled cephalo-caudal. After sterile preparation and administration of local anesthesia, a 22-gauge 10-mm radiofrequency (RF) needle was inserted and advanced toward the suprascapular notch

PRF treatment: The operator turns on the PRF for 3 min (2 cycles).
The placebo group, after the location and same needle insertion, receive an injection of xylocaine (also could provide pain relief), but without connecting the machine to the RF needle.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain, measured using Visual Analogue Scale (VAS) at baseline, at 1 week, 3 months and 6 months

Secondary outcome measures
1. Range of Motion (ROM): ROM at flexion, extension, abduction, external rotation and internal rotation (active and passive)
2. Shoulder Pain and Disability Index (SPADI)
Measured at baseline, 1 week, 3 months, and 6 months

Overall study start date
01/01/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Adult patients (aged over 20 years)
2. Have chronic shoulder pain for 3 months, including osteoarthritis of glenohumeral, acromioclavicular joints, adhesive capsulitis, rotator cuff impingement

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Inflammatory arthritis (rheumatoid arthritis, ankylosing spondylitis, etc.)
2. Active synovitis in the joints
3. Advanced osteoarthritis
4. Referred pain in the shoulder
5. Neurological impairment
6. Bleeding problems
7. Major depression

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Taiwan

Study participating centre
I-Shou University
Kaohsiung
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Sponsor information

Organisation
I-Shou University (Taiwan)

Sponsor details
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Sponsor type
University/education

Website
http://www.isu.edu.tw/en1/index.htm

ROR
https://ror.org/04d7e4m76

Funder(s)

Funder type
University/education

Funder Name
E-Da University (Taiwan) ref: ISU 100-04-11

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