

The efficacy of pulsed radiofrequency on chronic shoulder pain

Submission date 20/11/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/03/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 21/10/2016	Condition category Signs and Symptoms	☐ 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

Contact name

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Contact details

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Additional identifiers

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Taiwan

824

Sponsor information

Organisation

I-Shou University (Taiwan)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration