

Acupuncture and rehabilitation in the painful shoulder: a blinded randomised multicentre study

Submission date 15/02/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

82045

Study information

Scientific Title

Acupuncture and rehabilitation in the painful shoulder: a blinded randomised multicentre study

Study objectives

The association of acupuncture and physiotherapy techniques for patients with chronic shoulder pain due to subacromial syndromes (rotator cuff tendinitis, subacromial bursitis and/or capsulitis), reduces pain and improves functionality to a higher degree than the application of physiotherapy alone. Moreover, the application of the former technique enables a reduction in the consumption of medication prescribed as conventional therapy, and also reduces the iatrogeny provoked by such medication, without itself producing any significant iatrogeny.

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

Health condition(s) or problem(s) studied

Shoulder pain

Interventions

1. Acupuncture and rehabilitation
2. Transcutaneous electrical nerve stimulation (TENS) (placebo) and rehabilitation

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in the Constant-Murley score.

Secondary outcome measures

1. Changes in the intensity of diurnal pain according to visual analogic scale
2. Changes in the intensity of night-time pain according to visual analogic scale
3. Dose of non-steroidal anti-inflammatory drugs (NSAIDs) taken during the study
4. Scale of credibility of the treatment

Overall study start date

01/02/2005

Completion date

28/02/2007

Eligibility

Key inclusion criteria

Patients referred to the Rehabilitation Services of health centres participating in the study and belonging to the Public Health System (Andalusian Public Health System and Murcia Public Health System). Patients presenting chronic symptoms of painful shoulder with a diagnosis of supraspinal tendinitis or subacromial bursitis. The treatment proposed is physiotherapy combined with acupuncture or with transcutaneous stimulation (TENS) - placebo. Patients will be informed of the study design and of the techniques to be employed, as well as of the possible risks (infection, lipothymia, hematomas). They will be informed that they are free to conclude their participation in the study at any time, and will suffer no kind of penalty for doing so, nor will they lose any of the benefits to which they are entitled.

Selection criteria:

Approval by the Ethics Committee of the reference hospital.

Criteria for inclusion:

1. Patients with a clinical diagnosis of subacromial syndromes (supraspinal tendinitis or subacromial bursitis) with an evolution period greater than 3 months
2. Prior radiograph (normal)
3. Informed consent
4. Unilateral complaint

The sample size was determined for a significance level of 0.05 and a power of 0.80, with a final average score of 70 on Constants Functional Evaluation Scale for the Shoulder for the experimental group (standard deviation = 17) and of 65 for the control group (standard deviation = 18), using a two-tailed test. According to data obtained from earlier studies, 188 patients are required for the experimental group and 199 for the control group. Assuming a drop-out rate of 20%, the final sample size was set at 226 patients for the experimental group and 239 for the control group.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

465

Key exclusion criteria

1. Surgery
2. Luxations or fractures in the proximity of the shoulder
3. Other significant traumas
4. Direct or indirect (in traction) observed during anamnesis and clearly related to the onset of the episode
5. Hypocoagulates
6. Generalised disorders of the muscular-skeletal system
7. Neurological disorders
8. Vascular trophic disorders in the lower limbs
9. Lymphoedema

Date of first enrolment

01/02/2005

Date of final enrolment

28/02/2007

Locations**Countries of recruitment**

Spain

Study participating centre

Unidad de Tratamiento del Dolor

Dos Hermanas

Spain

41700

Sponsor information**Organisation**

Foundation Progress and Health (Council of Andalusian Health Services) (Spain)

Sponsor details

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Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

Foundation Progress and Health, Investigation in Biomedicine, Program of Rational Use of Drugs (Fundacion Progreso y Salud, Convocatoria Investigacion en Biomedicina, Programa del Uso Racional del Medicamento, Convenio Consejeria de Salud e Instituto de Salud Carlos III) (Spain) (ref: 82045)

Funder Name

Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (136/04)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		14/10/2005		Yes	No
Results article		01/06/2008		Yes	No