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

Submission date
15/02/2005

Recruitment status
No longer recruiting

Registration date
04/04/2005

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Vscular 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