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Contributions of myofascial pain in diagnosis and treatment of shoulder pain

Submission date
11/02/2009

Recruitment status
No longer recruiting

Registration date
27/02/2009

Overall study status
Completed

Last Edited
11/07/2019

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

Protocol serial number
PI07/90924

Study information

Scientific Title
Effectiveness in the treatment of Subacromial Impingement Syndrome by dry needling of active myofascial trigger points: a randomised controlled trial

Study objectives
Shoulder pain is an important cause of morbidity and has a high prevalence and the alteration of the soft or periarticular tissue is the most common cause. One consistent hypothesis consists of

relating Subacromial Impingement Syndrome (SIS) and/orrotator cuff tendonitis with myofascial pain syndrome. Myofascial pain syndrome is associated with differentiated, linear band-like hardness of the muscle containing hyperalgesic zones called Myofascial Trigger Points (MTrPs), which cause nociceptive agents such as substance P, potassium and histamine, among many others, to be released. These agents sensitize peripheral nociceptors and nociceptive neurones in the spinal dorsal horn. The MTrP can be defined as a hyperirritable nodule that elicits local and, frequently, referred pain when pressured, situated in a palpable taut band formed by skeletal muscle fibres. With regard to clinical activity, MTrPs can be active or latent. Both cause dysfunction, but only active MTrPs produce spontaneous referred pain.

Hypotheses:
1. There is a correlation relation between the existence of active MTrPs and SIS and/or rotator cuff tendonitis
2. The provocation tests for SIS are very sensitive and may give positive results before the existence of active MTrPs
3. The dry needling of the active MTrPs would increase notably the efficiency of the treatment of SIS and/or rotator cuff tendonitis

Therefore, the aims and design of the study cover two aspects: diagnosis and treatment of SIS and rotator cuff tendonitis

Aims regarding diagnosis:
1. Identification of any correlation between the existence of active MTrPs and SIS and rotator cuff tendonitis
2. Identification of any correlation between the results of provocation tests for SIS and the existence of active MTrPs
3. Evaluation of the diagnostic reliability of provocation tests for SIS, using NMR and ultrasonography as standard tests
4. Evaluation of the diagnostic reliability of physical exploration for active MTrPs, using ultrasonography and elastography as a gauge. This aim reflects the search for an imaging test that might be able to diagnose MTrPs

Aims regarding treatment:
5. Evaluation of the efficacy of dry needling of active MTrPs in the treatment of SIS and rotator cuff tendonitis compared to standard clinical protocols

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Clinical Research of Aragon (Comité de Etica de Investigación Clinica de Aragón), approved on 17/01/2008 (ref: PI07/21)

Primary study design
Interventional

Study design
Observational study (on diagnosis) followed by randomised controlled trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Myofascial pain, shoulder pain, subacromial impingement syndrome

Interventions
Five health centres in the city of Zaragoza take part in this study.

In the randomise controlled trial, the subjects included in the study will be randomised (with a hidden sequence) to two sets of experimental conditions:
1. Protocolised treatment based on active and passive joint repositioning, stabilisation exercises, stretching of the periarticular shoulder muscles and postural rehabilitation.
2. The previously described protocolised treatment with the addition of dry needling of active MTrPs on the supraspinatus, infraspinatus, subscapularis and teres minor muscles using Hong's fast-in and fast-out technique, once for each active MTrP and accompanied by a cold spray to reduce the painful post-needling sensation. Only one needling will be performed in each session with an interval of 8 days between sessions. In total each participant will receive three dry needling sessions.

The purpose of these treatment methods is to isolate the efficacy of dry needling in the treatment of rotator cuff tendonitis and/or SIS.

Training and standardisation sessions will be held for both protocols so that the intervention will be the same for all subjects in the study. The treatment will consist of 15 physiotherapy sessions and the measuring of dependent variables will be made during the initial visit and at the end of the treatment. The final assessment will be performed by a blinded evaluator.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Joint restriction measured by inclinometer: flexion-extension movements, abduction-adduction movements and outward-inward rotation movements
2. Pain on elevation in the scapular plane measured by score on Visual Analogical Scale and location of pain
3. Existence of active MTrPs in supraspinatus, infraspinatus, subscapularis and teres minor measured by algometry
4. Function Constant Test

The outcomes above will be assessed at the following time-points:
T0: At the beginning of the study (inclusion point)
T1: At the end of treatment (after 15 physiotherapy sessions)
T2: 3 months after the end of treatment

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/10/2009

Eligibility

Key inclusion criteria
1. Patients belonging to five health centres in the city of Zaragoza (Spain)
2. Both males and females, over the age of 18
3. Diagnosis of rotator cuff tendonitis and/or SIS by GP
4. Functional limitation and pain above 50% of the range of movement in flexion, abduction in the scapular plane and outward medial rotation
5. Patients who give their consent after being informed about participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Previous surgery for SIS
2. Invalidity, pain or sudden loss of strength after suffering a traumatism that suggests another serious condition
3. Other red flag signs indicating systemic disease
4. Inability to attend intervention sessions or refusal to participate

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Spain

Study participating centre

C.S. Andador Aragüés del Puerto S/N.
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Sponsor information

Organisation
Aragones Institute of Health Science (Instituto Aragonés de Ciencias de la Salud) (Spain)

ROR
https://ror.org/05p0enq35

Funder(s)

Funder type
Government

Funder Name
Carlos III Health Institute, Ministry of Health and Consumption (Spain) (FIS no. PI07/90924)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017	11/07/2019	Yes	No
Protocol article	protocol	24/07/2009		Yes	No