

# Contributions of myofascial pain in diagnosis and treatment of shoulder pain

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<b>Registration date</b> 27/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2019	<b>Condition category</b> 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

**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/or rotator 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 Clínica de Aragón), approved on 17/01/2008 (ref: PI07/21)

#### **Study design**

Observational study (on diagnosis) followed by randomised controlled trial

#### **Primary study design**

Interventional

#### **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 randomised 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?
<a href="#">Results article</a>	results	01/01/2017	11/07/2019	Yes	No
<a href="#">Protocol article</a>	protocol	24/07/2009		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes