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Effects of manual therapy for thoracic muscle pain

Submission date
20/06/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
29/03/2016

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Skeletal muscles (muscles that are under our control, allowing us, for example, to move and maintain our posture) are electrically active, and the signals measured from skeletal muscle cells can be used to detect medical problems. When we are resting, our skeletal muscles are normally electrically inactive, but pain can cause an increase in electrical activity. This activity can be measured using an instrument called an electromyograph. This study will use an electromyograph to find out how well a new spinal manipulation technique developed for relieving pain in thoracic spine muscles (muscles in the middle of your back) performs compared to an established manipulation technique. If the new technique results in greater pain relief than the conventional treatment, the electromyograph will record less electrical activity.

Who can participate?
Participants aged between 18 and 30 with acute or chronic pain in their thoracic spine muscles.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in group 1 undergo the new spinal manipulation technique. Group 2 are treated using the established technique. Pain and tenderness felt by each participant and the electromyography activity of their thoracic spine muscles are measured before treatment begins, immediately after the treatment and a week after treatment.

What are the possible benefits and risks of participating?
Not provided at registration

Where is the study run from?
Alcalá University (Spain)

When is the study starting and how long is it expected to run for?
July 2014 to October 2014

Who is funding the study?
Alcalá University (Spain)

Who is the main contact?
Dr Daniel Pecos-Martin
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Contact information

Type(s)
Scientific

Contact name
Dr Daniel Pecos-Martin

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28871

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Manual therapy effects on the electromyographic activity of the thoracic erector spinal muscles

Study objectives
An anterior/posterior articular manipulation technique on the thoracic spine produces better changes in electromyography activity and the pain related with erector spinal muscle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Alcalá ethics committee, 3/2/2014, ref. M2013/044/20140131

Study design
Single-blind randomized clinical trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Subjects with localized pain in the thoracic region of the back. Musculoskeletal pain related to activity.

Interventions
1. Experimental group: application of a PA contact mobilization using the T7 vertebra pisiforme about 3 minutes, with 20 seconds interval, with a frequency of 1 to 2 Hz. The mobilization amplitude grade III was applied.
2. Placebo group: application of a PA contact mobilization using the T7 vertebra pisiforme about 3 minutes, with 20 seconds interval, with a frequency of 1 to 2 Hz. The mobilization to a lower grade was applied as described by Maitland

Intervention Type
Procedure/Surgery

Primary outcome measure
Electromyography activity of thoracic spine muscles

Secondary outcome measures
Pain in thoracic spine muscles

The primary and secondary outcomes will be measured before treatment, immediately after and, finally, a week later.
Instruments used:
1. Pain: VAS
2. Tenderness: Algometry
3. Muscle activity: superficial electromyography

Overall study start date
01/07/2014

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Acute or chronic pain in the thoracic spine of nonspecific origin
2. Aged 18 to 30 years
3. Body Mass Index (BMI) < 29

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Previous history of surgery
2. Cardiovascular disorders
3. Neurological, musculoskeletal, osteoporosis, tumor, cancer diseases, radicular pain and / or neuropathy

Date of first enrolment
01/07/2014

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Alcalá
Alcalá de Henares
Spain
28871

Sponsor information

Organisation
Alcalá University (Spain)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04pmn0e78

Funder(s)

Funder type
University/education

Funder Name
Alcalá University (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/03/2017		Yes	No