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Effectiveness of deep dry needling in active miofascial trigger points in the reduction of non-specific cervical pain

Submission date
09/10/2011

Recruitment status
No longer recruiting

Registration date
08/11/2011

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Miofascial pain syndrome is another way to describe muscle pain. A lot of people have trigger points on their shoulder area that cause pain and tightness when stressed or injured. Physical therapy treatment of trigger points can be either conservative or invasive. They are usually treated by massages. Another more invasive option is known as dry needling. This is when needles are placed into the skin around one cm deep to penetrate the trigger point. Recent research has shown that deep dry needling of trigger points can improves pain pressure threshold (PPT) and joint ranges of motion (ROM) of the treated area. The aim of this study is to know if deep dry needling of myofascial trigger points of cervical (neck) muscles is effective in helping pain of these points in patients with non specific cervical pain.

Who can participate?
Adults aged 18 and older who are suffering from neck pain in the last three months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive invasive physical therapy and have deep dry needling in certain trigger points and stretching of the muscles after the dry needling. Those in the second group receive the stretching but not the dry needling. All participants receive two sessions a week over two years. There are assessed for pain levels and have follow up physical therapy sessions after the treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improvements with their physical health and a reduction in pain. There is a risk of pain that can develop over 48 hours after the treatment.

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

When is the study starting and how long is it expected to run for?
June 2011 to December 2013

Who is funding the study?
Carlos III National Health Care Institute (Spain)

Who is the main contact?
Professor Ester Cerezo-Téllez

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
26/2010

Study information

Scientific Title
Effectiveness of deep dry needling in active miofascial trigger points in the reduction of non-specific cervical pain

Study objectives
Deep dry needling of miofascial active trigger points of cervical muscles in patients suffering frominespecific cervicalgya is effective in patient's pain dimminution.

The prevalence of Miofascial active trigger points and non-specific cervicalgia are related.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Clinical Trials of Area 3 at University Hospital of Alcalá de Henares, Madrid (Spain), July 2010, ref: 26/2010
2. Research Central Comission of Ethics of "Gerencia Area 3 Atención Primaria", 13 April 2011, ref: 44/11

Study design
Simple blinded randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain

Interventions
Patients in the group of "Invasive Physical Therapy" will be treated with deep dry needling in all miofascial active trigger points found in cervical musculature described. They were also be applied analytical passive stretching of the muscles where deep dry needling have been applied.

Patients in "control group" (minimal intervention group) will receive the same analytical passive stretching in the muscles where active MTrPs have been found than patients in the group of "Invasive Physical Therapy." In both groups, the intervention program will consist of 2 sessions a week over a period of 2 weeks, 4 sessions of physiotherapy in total. There will be a physiotherapy review pre-intervention as baseline, a second assessment physiotherapy during the intervention (after the 2nd session of treatment) and third assessment of physical therapy after finishing the intervention (at the end of the 4th session of physical therapy), and 4 ratings physiotherapeutic track 15, 30, 90 and 180 days.
In the event that the patient no longer reported pain (VAS = 0) before the end of the scheduled physical therapy sessions, physical therapy should be stopped keeping follow-up assessments provided.

Follow-up
After first baseline assessment pre-intervention assessments were scheduled during physical therapy.

Reviews post-intervention (4 days after physical therapy treatment so that post-needling pain does not influence the assessment):
1. After physical therapy treatments and before the third session of physical therapy
2. After the fourth physical therapy treatment
3. Assesments during the treatment
4. Physical therapy evalutations were conducted as follow-up at 15, 30, 90 and 180 days respectively.

Each group will be treated by a different physiotherapist. Before starting the study, consensus intervention meetings will be held to ensure that analytical passive stretching of the muscles in both groups is identical. All physical therapy participants in the study are specialists in physical therapy diagnosis and the Miofascial pain syndrome.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Subjective pain using Visual Analogue Scale (VAS)

Key secondary outcome(s))
1. Demographic
2. Antropometrics: weight and height
3. Antecedents: evolution time of the problem, previous traumatisms, etc.
4. Assesment of muscles (trapezius, levator scapulae, multifidus, esplenius cervicis) to find presence of Miofascial Active trigger points
5. Pain pressure threshold of active MTrP in mentioned musculature using algometry Foix (Wagner Intruments, USA) in Kg/cm2
6. Cervical articular range of movement (Flexoextension, rotation and lateral flexion (inclination)) using CROM goniometer in degrees
7. Strength (Flexion, extension, rotation and lateral flexion (inclination)) using digital dinamometer Microfet 2 (Hoogan Health Industries, USA) in Newtons
8. If patients have any analgesics (Non steroideal anti-inflamatory drugs)

Completion date
30/12/2013

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Present a diagnostic of non specific cervical chronic (more than 3 months with pain sintomatology)
3. Neck pain (with non-traumatic antecedents, neurologic infection, discal problems)
4. Present Miofascial active Trigger Points in multifidus, splenius cervicis, levator scapulae and trapezius muscles
5. The pain must be on or over 3 points in Visual Analogue Scale
6. The patients must have signed the informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Patients who present any contraindication for physical therapy treatment as deep dry needling (infection, fever, hypothyroidism, insuperable afraid of needles, injuries on the skin above the needling, metal allergy, cancer, systemic diseases)
2. Psycotic and depresive patients

Date of first enrolment
01/06/2011

Date of final enrolment
30/12/2013

Locations

Countries of recruitment
Spain

Study participating centre
University of Alcalá
Madrid
Spain
E-28871

Sponsor information

Organisation
University of Alcalá, Madrid (Spain)

ROR
https://ror.org/04pmn0e78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Carlos III National Health Care Institute (Spain)

Funder Name
Mapfre Foundation (Spain)

Alternative Name(s)
Mapfre Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Argentina

Funder Name
Investigator initiated and funded

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	01/09/2016	18/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes