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The efficacy of acupotomy combined with muscle activation for patients with myofascial chronic neck pain

Submission date
15/05/2018

Recruitment status
No longer recruiting

Registration date
16/05/2018

Overall study status
Completed

Last Edited
16/05/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Neck pain is the fourth leading cause of disability in middle age. Several factors are linked to the etiology (cause) of neck pain, and myofascial trigger points (sensitive spots in soft tissue) are the most common reason for chronic neck pain. The aim of this study is to investigate the effects of acupotomy (a minimally invasive surgery of traditional Chinese medicine) combined with muscle activation in patients with myofascial chronic neck pain.

Who can participate?
Patients aged 18 to 75 with neck pain

What does the study involve?
All patients undergo acupotomy treatment once every two days , and then the muscles surrounding the cervical spine are strengthened or stretched twice a day. Disability, pain and cervical range of motion are assessed before the first treatment, immediately after the treatment and in the follow-up (1 week, 4 and 8 weeks after the last treatment).

What are the possible benefits and risks of participating?
The acupotomy operation may quickly relieve pain and functional limitations in patients with myofascial chronic neck pain. Selective muscle activation may provide a long-lasting healing effect by preventing the occurrence of fascial trigger points. The risk of manipulation is bleeding, pain and infection.

Where is the study run from?
The affiliated hospital to Changchun university of Chinese medicine (China)

When is the study starting and how long is it expected to run for?
October 2016 to May 2018

Who is funding the study?
Jilin Provincial Science and Technology Plan of China

Who is the main contact?
Dr Shao jun Li

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20180510ABAM

Study information

Scientific Title
The efficacy of acupotomy combined with muscle activation for patients with myofascial chronic neck pain

Study objectives
The trialists hypothesize that acupotomy combined with muscle activation can provide long-lasting and stable efficacy for the patients with chronic myofascial neck pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of affiliated hospital to Changchun university of Chinese medicine, 15 /11/2017, ref: CCZYFYLL 2017 approval - 057

Study design
The clinical data of patients with chronic fascial neck pain was studied retrospectively

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Neck pain is the fourth leading cause of disability in middle age. Several factors link to the etiology of neck pain, and myofascial trigger points is the common reason for chronic neck pain.

Interventions
The clinical data of patients with chronic fascial neck pain was studied retrospectively. All the patients underwent the treatment of acupotomy, and then the muscles surrounding the cervical spine were strengthened or stretched. The acupotomy operation was performed once every two days. Muscle activation training was practiced twice a day. The duration of follow-up was 8 weeks.

Neck Disability Index (NDI) was used to assess psychological and disability variables. NDI consists of 10 items that evaluate different functional activities. Each item is divided into six levels: from 0 (no disability) to 5 (completely disabled). The total score is obtained by adding the score of each item and multiplying it by 2. Higher scores indicate more severe pain and dysfunction. All the patients who were included in the study had to complete all these questionnaires before the first treatment, immediately after the treatment and in the follow-up. The duration of follow-up was 1 week, 4 and 8 weeks after the last intervention. Visual Analogue Scale (VAS) was utilized in assessment of the degree of cervical pain. It was scored 0-10 (0 being no pain and 10 being unbearable pain). The cervical range of motion (ROM) was used to evaluate cervical range motion. As with NDI, the assessment was performed before, immediately after treatment and during the follow-up period.

Intervention Type
Other

Primary outcome measure
1. Degree of cervical pain, assessed using the visual analogue scale before the first treatment, immediately after the treatment and in the follow-up (1 week, 4 and 8 weeks after the last intervention)
2. Cervical range of motion, assessed before the first treatment, immediately after the treatment and in the follow-up (1 week, 4 and 8 weeks after the last intervention)

Secondary outcome measures

Psychological and disability variables, assessed using the Neck Disability Index (NDI) before the first treatment, immediately after the treatment and in the follow-up (1 week, 4 and 8 weeks after the last intervention)

Overall study start date
01/10/2016

Completion date
10/05/2018

Eligibility

Key inclusion criteria
1. Subjects with neck pain
2. Suffering from neck pain for at least 3 months
3. The pain intensity was higher than 2 on a visual analogue scale (VAS)
4. Neck pain could be provoked by either neck postures or neck movement
5. Restricted cervical range of movements (flexion, extension, rotation, and side-bending)
6. Males or females aged 18 to 75 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Orofacial pain and temporomandibular disorders
2. A history of traumatic injuries (e.g., contusion, fracture, and whiplash injury)
3. Systemic diseases such as fibromyalgia, systemic erythematous lupus, and psoriatic arthritis
4. Neurologic disorders
5. Concomitant medical diagnosis of any primary headache (tension type or migraine)
6. Patients who had coagulopathy, abnormal findings on their ECG
7. Cervical spine surgery
8. Clinical diagnosis of cervical radiculopathy or myelopathy
9. Needle phobia

Date of first enrolment
02/10/2016

Date of final enrolment
10/05/2018

Locations

Countries of recruitment
China

Study participating centre
The affiliated hospital to Changchun university of Chinese medicine
China
130022

Sponsor information

Organisation
The affiliated hospital to Changchun university of Chinese medicine

Sponsor details
Gong nong Rd. No.1478
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-

Sponsor type
Not defined

ROR
https://ror.org/035cyhw15

Funder(s)

Funder type
Government

Funder Name
Jilin Provincial Science and Technology Plan of China

Results and Publications

Publication and dissemination plan
To be submitted to BMC Musculoskeletal Disorders.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (https://figshare.com). The data of VAS, NDI, and ROM will be shared and the pictures will be shared too. The data will become available after the paper is published, and will be available to everyone permanently.

IPD sharing plan summary
Stored in repository