Clinical Trial Protocol
Iranian Registry of Clinical Trials
06 Sep 2022

Comparison of effect of dry needling, physiotherapy, and sham dry needling in cervicogenic headache- A randomized controlled clinical trial

Protocol summary

Study aim
Comparison of effect of dry needling, physiotherapy, and sham dry needling in cervicogenic headache

Design
A triple blind randomized clinical trial consisting of three routine physiotherapy groups and a routine physiotherapy with dry needles and a routine physiotherapy with a placebo needle.

Settings and conduct
Patients in the routine physical therapy group for fifteen sessions, three times a week, will undergo physiotherapy including electrical stimulation, surface heat, neck ultrasound and neck stabilization exercises. In dry needle group, in addition to the above items, dry needle will be performed according to the Dommerholt method for 4 sessions and the second, fifth, eighth and twelfth sessions will be performed at the active trigger points of the upper trapezius muscles, cervical erector spine muscles and sternocleidomastoid. In the placebo group, the needle is very superficial and at a point away from active trigger points during 4 sessions in the muscles, so that we can differentiate the effects of placebo needle dry from its actual effects. The assessments will be done before the treatment immediately after treatment, one month later, three and six months later.

Participants/Inclusion and exclusion criteria
Unilateral headache Starting in the neck Pain aggravated by neck movement Restricted cervical range of motion Joint tenderness in the joints of the upper cervical spine Active trigger point in neck muscles

Intervention groups
The cervicogenic headache are randomly divided into three groups. The first group routine physiotherapy, the second group routine physiotherapy and dry needle, the third group routine physiotherapy and placebo needle

Main outcome variables
The severity and frequency of headaches, Neck range of motion, pressure Pain threshold and tenderness at the trigger point of the muscles, Function of deep neck flexor muscles, neck proprioception

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20180721040539N1
Registration date: 2018-09-24, 1397/07/02
Registration timing: registered_while_recruiting

Last update: 2018-09-24, 1397/07/02
Update count: 0

Registration date
2018-09-24, 1397/07/02

Registrant information
Name
Roghayeh Mousavi-khatir
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3219 2832
Email address
r-mousavi@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
Scientific title
Comparison of effect of dry needling, physiotherapy, and sham dry needling in cervicogenic headache - A randomized controlled clinical trial

Public title
The effect of dry needling in cervicogenic headache - A randomized controlled clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Unilateral pain starting in the neck and radiating to the frontotemporal region Pain aggravated by neck movement Restricted cervical range of motion Joint tenderness in at least one of the joints of the upper cervical spine (C1-C3) Headache frequency of at least 1 per week over a period greater than 3 months Active trigger point in the suboccipital and upper trapezius and sternoclidomastoid muscles

Exclusion criteria:
Cervical radiculopathy A history of spinal or shoulder trauma or spinal surgery History of physical therapy intervention in the neck and shoulder region within the previous 6 months Diagnosed primary headache Needle phobia

Age
From 19 years old to 60 years old

Gender
Both

Phase
N/A

Groups that have been masked
- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
At first, a physiotherapist with ten years of experience perform patient’s physical examination. If they meet the conditions for entry into the study, and don’t have exclusion criteria, a randomization into three groups (control and DN group, sham DN group) was performed by packed envelopes via blind independent researcher to aim of allocation concealment.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In sham dry needling group, the patient will not be aware of the fact that he/she does not receive the actual dry needling. The assessor and therapist will two different individuals and assessor blind to intervention. Also, statistical analysis will be done by a person who is blind to grouping

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date
2018-06-10, 1397/03/20
Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.071

Health conditions studied

1
Description of health condition studied
cervicogenic headache patients
ICD-10 code
G44.0
ICD-10 code description
Other headache syndromes

Primary outcomes

1
Description
intensity of the headache
Timepoint
Before treatment, immediately after treatment, one, three and six month later
Method of measurement
questionnaire

2
Description
headache frequency
Timepoint
Before treatment, immediately after treatment, one, three and six month later
Method of measurement
questionnaire
Neck range of motion

Timepoint
Before treatment, immediately after treatment, one , three and six month later

Method of measurement
Goniometry

Function of deep neck flexor muscles

Timepoint
Before treatment, immediately after treatment, one , three and six month later

Method of measurement
pressure biofeedback

Pressure pain threshold and tenderness at the trigger point of the muscles

Timepoint
Before treatment, immediately after treatment, one , three and six month later

Method of measurement
Algometer

Neck proprioception

Timepoint
Before treatment, immediately after treatment, one , three and six month later

Method of measurement
laser pointer and software

Quality of life

Timepoint
Before treatment, Immediately after treatment, One month later, Three months and Six month later

Method of measurement
Quality of life questionnaire

Secondary outcomes

Functional rating index

Timepoint
Before treatment, Immediately after treatment, One month later, Three months and Six month later

Method of measurement
Functional rating index-questionnaire

Intervention groups

1
Description
Intervention group 1: Routine physiotherapy and dry needle

Category
Rehabilitation

2
Description
Intervention group 2: Routine physiotherapy and placebo needle

Category
Rehabilitation

3
Description
Intervention group 3: Routine physiotherapy

Category
Rehabilitation

Recruitment centers

1
Recruitment center
Name of recruitment center
Ayatollah Rouhani Educational and Therapeutic Center

Full name of responsible person
Roghayeh Mousavi-Khatir

Street address
Ayatollah Rouhani Educational and Therapeutic Center, Ganjafrooz Street, Babol, Mazanda, Iranran

City
Babol

Province
Mazandaran

Postal code
۵۴۷۷۴-۶۷۱۷۴

Phone
+98 11 3219 4641

Fax
+98 11 3219 0181

Email
r-mousavi@mubabol.ac.ir

Web page address
http://rohani.mubabol.ac.ir/

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr Reza Ghadimi
Street address
University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 7667

Email
rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Khodabakhsh Javanshir

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 4641

Email
kjavanshir@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Roghayeh Mousavi-Khatir

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation, University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 4641

Email
r-mousavi@mubabol.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Roghayeh Mousavi-Khatir

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation, University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 4641

Email
r-mousavi@mubabol.ac.ir

Sharing plan
Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available