Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of the immediate and after one week effect of dry needling on chronic non-specific low back pain women with hamstring shortness: A placebo controlled RCT

Protocol summary

Study aim

The purpose of this clinical trial is to investigate the immediate effects of dry needles on the flexibility of hamstring muscle in women with chronic non-specific low back pain.

Design

This study is a controlled clinical trial, double blind, randomized, with parallel groups.

Settings and conduct

The place of the study is the physiotherapy clinic of the Tehran University of Medical Sciences rehabilitation faculty. After ensuring about inclusion criteria and after obtaining written consent, the participant is included in the study. Before the intervention, the desired variables including pain intensity, hamstring length and functional disability are investigated by randomized procedure. Participants are randomly assigned to a dry needling group and control group. Immediately and one week after the intervention, the outcome variables are examined. In this study, the assessor and the participants are blind.

Participants/Inclusion and exclusion criteria

In this study, women with chronic non-specific low back pain with hamstring shortness can be included.

Intervention groups

In the intervention group, the hamstring muscle is needling at the muscle end plates for one session, but in the control group, the points determined by the needle are hit.

Main outcome variables

Functional disability was evaluated using the functional rating index questionnaire, the intensity of low back pain by using visual analog scales, the length of the hamstring muscle by the passive knee extension and the middle finger to floor distance test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180511039612N1**
Registration date: **2018-07-02, 1397/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-02, 1397/04/11**
Update count: **0**

Registration date

2018-07-02, 1397/04/11

Registrant information

Name

Mahnaz Bazzaz yamchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5377 3251

Email address

m-bazzaz@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the immediate and after one week effect of dry needling on chronic non-specific low back pain women with hamstring shortness: A placebo controlled RCT

Public title
immediate effect of dry needling on hamstring muscle flexibility

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic non-specific low back pain , without history of fracture in low back and thigh region Less than 80◦ of the passive knee extension (PKE) test Female gender Intensity of low back pain based on VAS , is being between 3-7 Do not be afraid of needle Do not use blood thinner such as Warfain No vascular disease No history of muscular disease such as Myopathy No Radicular pain in lower extermity Not pregnancy The duration of the low back pain should be more than 3 month No needle sensitivity Lack of epilepsy Lack of diabetes

Exclusion criteria:
Intolerance to the evaluation and treatment steps Acute low back pain and fracture in the low back and hip area between therapeutic sessions Unwillingness to continue cooperation

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign the participants to the dry needle treatment group and the control group, each participant is assigned a number and then, using the randomized block method, each of the numbers is assigned a drying needling or placebo group (1 or 2). These codes are placed inside sealed envelopes

Blinding (investigator's opinion)
Double blinded

Blinding description
Using sham needle in the placebo group will cause blindness to the participants. The use of sealed envelopes in the random allocation of participants in a therapeutic groups will result in blind assessments of the consequences.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of nursing and midwifery and rehabilitation schools of Tehran University of Medical

Street address
Ghods Ave , Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
0

Approval date
2018-04-15, 1397/01/26

Ethics committee reference number
IR.TUMS.FNM.REC.1397.4958

Health conditions studied

1

Description of health condition studied
Non-specific chronic low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of low back pain

Timepoint
Before , after and one week after intervention

Method of measurement
Visual analog scale

2

Description
hamstring muscle length

Timepoint
Before , after and one week after intervention

Method of measurement
Passive knee extension and finger to floor test

Secondary outcomes

1

Description
Functional disability

Timepoint
Before and one week after intervention

Method of measurement
Functional rating index

Intervention groups

1

Description
Intervention group:hamstring muscle is needling cone shape fast in-fast out during a therapeutic session at 3 points of muscle end plate for 1 minute at each point bilaterally.
Category
Rehabilitation

2

Description
Control group: on the muscle end plate is taping by sham needle for 1 minute at each point bilaterally.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy clinic,School of Rehabilitation,Tehran University of Medical Science
Full name of responsible person
mahnaz bazzaz yamchi
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Department of Physiotherapy ,School of Rehabilitation,Pitch-e Shemiran, Enghelab Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Saharian
Street address
Vice chancellor for research of Tehran University of Medical Science,6th floor, University central office ,Ghods Avenue,Keshavarz Blv
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
mahnaz bazzaz yamchi
Position
master student of Phisotherapy
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
...
When the data will become available and for how long
...
To whom data/document is available
...
Under which criteria data/document could be used
...
From where data/document is obtainable
...
What processes are involved for a request to access data/document
...
Comments