

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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 extremity 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

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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

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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 Physiotherapy

Latest degree

Bachelor

Other areas of specialty/work

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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