

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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

##### 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

**Street address**

Department of Physiotherapy, School of Rehabilitation, Pitch-e Shemiran, Enghelab Avenue

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m-bazzaz@razi.tums.ac.ir

**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 Physiotherapy

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

mahnaz bazzaz yamchi

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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**