Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of dry needling plus static stretching on pain, hamstring flexibility, disability, and balance in patients with chronic non-specific low back pain

Protocol summary

Study aim

If the use of dry needling combined with static stretching produces a greater reduction in pain in patients with low back pain, this method can be recommended for use in physiotherapy clinics to achieve a more effective treatment intervention in patients with chronic non-specific low back pain. This study can also show the consistency of the effects of three sessions of dry needling combined with static stretching over a one-week follow-up period.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, On 48 patients, Randomization by cards or envelopes Shuffling

Settings and conduct

This study is conducted at Hazrat Abolfazl Clinic in Tehran. In this study, assessments are done before interventions, after the interventions, and one week follow-up. In the intervention group after dry needling for 3 minutes (three points and each point for 1 minute), 3 sets of 2-minute hamstring muscle stretching are applied using an exercise band. In the control group in addition to Sham dry needling in the form of 10-gram monofilament, static stretching is administered the same as the intervention group. Both interventions are performed for 3 sessions with a frequency of once a day and 3 days a week.

Participants/Inclusion and exclusion criteria

Inclusion criteria Men and women with non-specific low back pain Decreased passive knee extension of more than 25 degrees Exclusion criteria Non-cooperation in carrying out treatment protocols Absence of the person in two consecutive treatment sessions

Intervention groups

In the intervention group, dry needling plus static stretching will be applied to the hamstring. Sham dry needling and static stretching will be applied in the control group.

Main outcome variables

Visual analog scale Passive knee extension test Functional rating index Timed up and go test Euro Qol questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058844N2**
Registration date: **2026-01-06, 1404/10/16**
Registration timing: **prospective**

Last update: **2026-01-06, 1404/10/16**
Update count: **0**

Registration date

2026-01-06, 1404/10/16

Registrant information

Name

Mahdi Esmaeeli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-04, 1404/11/15

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of dry needling plus static stretching on pain, hamstring flexibility, disability, and balance in patients with chronic non-specific low back pain

Public title
Effects of dry needling plus static stretching of hamstring muscle in chronic nonspecific low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women with non-specific low back pain Decreased passive knee extension of more than 25 degrees 12 weeks after the onset of low back pain Visual analog scale between 3 and 7 No contraindication for dry needling No history of other neuromuscular system disorders Ability to understand and follow the instructions
Exclusion criteria:
Non-cooperation in carrying out treatment protocols Absence of the person in two consecutive treatment sessions Inability to complete the pre and post assessments
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the participants were divided into two groups by a simple randomization by Cards or Envelopes Shuffling which were prepared according to their number and one of the names of the intervention or control was written on it. All patients have the same chance of being placed in any of the two groups. This study is a double-blind study. In this study, due to the use of sham dry needling, patients in the control group will be blinded of their placement in the intervention and control groups. Also, the assessor is blinded of the control and intervention groups and only knows them as groups A and B. Only the interventionist is aware of the research events completely.
Blinding (investigator's opinion)
Double blinded
Blinding description
The assessor is the researcher and during the assessments, he is not aware of the grouping of the patients and only knows them into two groups A and B. The use of sham dry needling in the control group causes the patient to be blinded to being in the control or intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Baqiyarallah University of Medical Sciences
Street address
3rd Floor, No 10, Rashidi Alley, Meghdad St, Pirouzi Ave
City
Tehran
Province
Tehran
Postal code
1766717194
Approval date
2025-12-13, 1404/09/22
Ethics committee reference number
IR.BMSU.REC.1404.152

Health conditions studied

1

Description of health condition studied
Non-specific low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Visual Analogue Scale
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
with a ruler from 1-10

2

Description
Passive knee extension test
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
By goniometer in degrees

3

Description
Functional rating index
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Questionnaire with 10 items and scores between 0 and 40 as a percentage

4

Description
Timed up and go test
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Time measured by a chronometer

5

Description
quality of life
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
European quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, patients received static stretching of the hamstring muscle in each treatment session after dry needling. Dry needling is preferred before static stretching with the aim of reducing muscle tension and allowing for more effective application of stretching in a greater range. A) Dry needling: A sterile disposable needle (0.25mm×0.60mm, SMC, Seoul, Korea) is used for dry needling. The patient is asked to lie prone on the bed and the Fast in Fast out technique is used deeply on three points of the hamstring muscle (long and short heads of the biceps femoris, semitendinosus and semimembranosus) for 3 minutes (1 minute at each point). The exact needle location is determined by connecting a line from the ischial tuberosity to the fibular head, and the needle enters the long and short heads of the biceps femoris muscle at 60% and 30% of this line, respectively. Another line from the ischial tuberosity is also connected to the medial femoral condyle, and at 60% of this line, the needle enters the semitendinosus and semimembranosus (29). The number of treatment sessions for dry needling is performed once a day, every other day, for 3 sessions (53). b) Static stretching: To apply static stretching, patients are asked to lie supine on the bed and, while maintaining the knee in extension, move the hip towards flexion using an exercise band, placing the hamstring muscle under maximum tension. This static stretching is applied in 3 sets of 2 minutes with 2 minutes of rest between sets. The number of treatment sessions for static stretching is performed once a day, every other day, for 3 sessions (18).
Category
Rehabilitation

2

Description
Control group: In the control group, in each treatment session, Sham dry needling will be performed by applying 10 grams of monofilament, and then static stretching will be applied according to the intervention group. The number of treatment sessions and the duration of the sessions will be the same as the intervention group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Abolfazl Clinic, Tehran
Full name of responsible person
Dr. Vahid Sobhani
Street address
No 1, 6/39 Ave, Niroo Havayi Blvd, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person
Dr. Vahid Sobhani

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mollasadra st, vanak sq sheykh bahayi st,Tehran,Iran

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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Mahdi Esmaeeli

Position
Elite Soldier (Researcher)

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Position
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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