

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing effects of cryotherapy and TENS on signs and symptoms of delayed onset muscle soreness in amateur athletes

Protocol summary

Summary

Purpose: To compare the effects of repeated use of cryotherapy and transcutaneous electrical nerve stimulation (TENS) on signs and symptoms following hamstring delayed onset muscle soreness (DOMS).
Design: Single blind. Participants: Amateur male soccer player. Inclusion criteria: Not any lower extremity injury during previous year and not any contraindication for using electrical stimulation or icing. Exclusion criteria: Any sensitivity to ice or electrical stimulation during the tests
Outcome measures: Pain intensity, AROM, thigh girth and triple hop distance

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100230083N1**
Registration date: **2017-04-19, 1396/01/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-19, 1396/01/30

Registrant information

Name

Kazem Malmir

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of cryotherapy and TENS on signs and symptoms of delayed onset muscle soreness in amateur athletes

Public title

Effects of cold therapy and electrical stimulation on signs and symptoms of muscle soreness due to overwork in amateur athletes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No lower extremity injury during previous year; No contraindication for using electrical stimulation or icing; No sensitivity to ice or electrical stimulation during the tests; Not any heavy training two weeks before performing the tests. Exclusion criteria: Any burning in the skin due to TENS or any frostbite due to cryotherapy; Any unsatisfactory feeling in participants to continue testing process

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rehabilitation and Nursing And Midwifery School of Tehran University of Medical Sci

Street address

Tehran Province, Tehran, District 6, Nosrat St

City

Tehran

Postal code

1419733171

Approval date

2016-09-03, 1395/06/13

Ethics committee reference number

IR.TUMS.REC.1395.2788

Health conditions studied

1

Description of health condition studied

Delayed onset muscle soreness

ICD-10 code

M62.9

ICD-10 code description

Disorder of muscle, unspecified

Primary outcomes

1

Description

Active knee extension range of motion

Timepoint

Before, 24, 48 and 72 hours after inducing delayed-onset muscle soreness

Method of measurement

Digital goniometer

2

Description

Triple hop distance

Timepoint

before, 24, 48 and 72 hours after inducing delayed-onset muscle soreness

Method of measurement

Triple hop distance test

3

Description

Thigh girth

Timepoint

before, 24, 48 and 72 hours after inducing delayed-onset muscle soreness

Method of measurement

Flexible meter(upper-middle-lower regions of the thigh)

4

Description

Pain intensity

Timepoint

before, 24, 48 and 72 hours after inducing delayed-onset muscle soreness

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

N/A

Timepoint

N/A

Method of measurement

N/A

Intervention groups

1

Description

Inducing delayed-onset muscle soreness (DOMS) [Independent variable] [for all groups]: For inducing delayed onset muscle soreness in the hamstrings, the participant is in the kneeling position on a bed and the hands are by the sides. Distal of the legs is secured using a strap. The participant is asked to bend forward from the knees as further as possible. He is instructed not to bend the hip joints or the spine. In this way, the hamstrings have to control, eccentrically, the lowering of the thigh, pelvic and trunk segments as a rigid lever. The procedure consists of 12 sets including, six repetitions. Ten seconds and 2 min rest are allowed between each repetition and set, respectively.

Category

Rehabilitation

2

Description

Trans cutaneous Electrical Nerve Stimulation(TENS group): Transcutaneous electrical nerve stimulation is applied by an ITO stimulator (Model 1207, ITO, Co., Ltd, Japan). The participant is in the prone position. One pair of rubber electrodes is placed longitudinally on the most painful site of the musculotendinous junction of the hamstrings in the lower one-third of the muscle. TENS is applied once in a day for three consecutive days. Frequency, pulse width and duration are set at 110 Hz, 200 μ s, and 20 min, respectively. Intensity is increased up to a sensory level, that is, the participant should feel a paresthesia with no muscle contraction

Category

Rehabilitation

3

Description

Cryotherapy(cryotherapy group): The participant is in the prone position. A wet towel is put on the hamstrings muscle. Ice bag containing mixed pieces of ice and water is put on the towel and covered by another towel. The intervention lasts for 20 min. The cryotherapy protocol consists of three repetitions daily (8-hour intervals) for three consecutive days. The size of the ice bag is chosen according to the contour of the hamstrings. Any adverse effect of icing is monitored by the researchers in the first session.

Category

Rehabilitation

4

Description

No intervention after inducing DOMS (control group): No intervention was prescribed for the control group after inducing DOMS.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation of Tehran University of Medical Sciences

Full name of responsible person

Behzad Moradi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Massoud Younesian

Street address

Physical Therapy Department, School of Rehabilitation, Enghelab Street, Tehran, Iran

City

Tehrn

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malmir

Position

Faculty member

Other areas of specialty/work

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Full name of responsible person

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Position

Faculty member

Other areas of specialty/work

Street address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty