Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Kazem Malmir
Name of organization / entity
Tehran University of Medical Sciences
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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 commette of Rehabilitation and Nursing And Midwify 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 µs, 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
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Position
Faculty member

Other areas of specialty/work

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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