Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effects of cryotherapy and cryostretch on clinical and functional outcomes in athletes with acute hamstring muscle strain

Protocol summary

Summary

(1) Objectives: The aim of the present study is compare the effects of cryostretching and cryotherapy on pain, range of motion and functional status in athletes with acute hamstring muscle strain.(2) Design: This is a randomized clinical trial on 37 athletes with acute hamstring muscle strain which will be divided to two groups (cryotherapy and cryostretch group) randomly. The patients will not aware about her/his group. (3) Setting and conduct: a) The patients will be divided to two groups randomly. Both treatment regimens will be augmented by a daily home treatment program for five consecutive days. In the cryotherapy group ice bag will wrap around injured location for 20 minutes in prone position. In cryostretch group, participants will perform static stretch of hamstring muscle hold for 30 seconds after 20 minutes cold application. Pain will be measured based on visual analog scale (VAS), knee range of motion during active and passive knee extension test will be measured using inclinometer and functional status will be measured using the Persian version of Lower Extremity Functional Scale (LEFS). Pre-treatment and post-treatment assessments will be performed on day 1 and day 6. The variables will be compared between groups. (4) Participants: Athletes with acute hamstring strain. Inclusion criteria: Elite male or female athlete between 18-40 years؛ Athletes with acute first or second degree strain of hamstring؛ Participants will be visited in sports physical therapy clinic within 72 hours after injury؛ Participants have no hypersensitivity or cold intolerance؛ No history of lower limb injury such as fracture or injury that required surgery within the past 6 months ؛Participants agree not to take NSAID medication during the study. Exclusion criteria: If the patient dose not complete the treatment program and missing the sessions. The patient will stop his/her program any time he/she wants.(5) Intervention: Cryotherapy and cryostretch for 5 sessions.(6) Variables: The main variables are pain, active and passive knee extension ROM and functional status.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030726957N1**
Registration date: **2016-06-19, 1395/03/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-19, 1395/03/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2016-04-29, 1395/02/10

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of cryotherapy and cryostretch on clinical and functional outcomes in athletes with acute hamstring muscle strain

Public title

The effect of stretching exercise and cryotherapy in hamstring strain management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The athletes participate in sports activity for at least two years and three times per week for a minimum of 2 hours each time؛ Male or female athlete between 18-40 years old؛ Athletes with acute first or second degree strain of hamstring; Pain evoked by resisted prone knee flexion and passive tension testing using؛ Participants are visited in sports physical therapy clinic within 72 hours after injury؛ Participants had no hypersensitivity or cold intolerance؛ participant had no sign of complete muscle disruption؛ no history of lower limb injury such as fracture or injury that required surgery within the past 6 months؛ No history of malignant or neurologic disease؛ No clinical finding showing radiculopathy؛ No hip flexor muscle shortness (as diagnose by Thomas test)؛ Participants agree not to take NSAID medication or receive any other form of treatment during the study. Exclusion criteria: If the patient dose not complete the treatment program and missing the sessions. The patient will stop his/her program any time he/she wants.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will performe using random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

6th floor, Central orzanization of Tehran university of Medical Science, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2016-04-17, 1395/01/29

Ethics committee reference number

IR.TUMS.REC.1395.2411

Health conditions studied

1

Description of health condition studied

muscle strain

ICD-10 code

M62.6

ICD-10 code description

Muscle strain

Primary outcomes

1

Description

Pain

Timepoint

On day 1 (before first treatment session) and day 6 (after fifth treatment session)

Method of measurement

Visual Analog Scale (VAS)

2

Description

Active and passive knee extension range of motion

Timepoint

On day 1 (before first treatment session) and day 6 (after fifth treatment session)

Method of measurement

Knee extension test using inclinometer

3

Description

Functional status level

Timepoint

on day 1 (before first treatment session) and day 6 (after fifth treatment session)

Method of measurement

Lower Extremity Functional Scale (LEFS)

Secondary outcomes

1

Description

_

Timepoint

_

Method of measurement

_

Intervention groups

1

Description
Superficial cooling by ice bag composed of crushed ice for intervention group(cryotherapy) 2
Category
Rehabilitation

2

Description
Static stretching exercise of hamstring for intervention group(cryostretch) 1
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Sport Physicaltherapy Center
Full name of responsible person
Nastaran Ghotbi
Street address
No 204, Floor 2, Asemane Sardar Building, Sardar Jangal St
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Masud Yunesian, Vice chancellor for research
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6th floor, Central organization of Tehran University of Medical Sciences, Keshavarz Blvd
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Tehran
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,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

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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