

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

##### Name

Leyla Sefiddashti

##### Name of organization / entity

Department of Physiotherapy

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 4133

##### Email address

l-sefiddashti@razi.tums.ac.ir

##### 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

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor for research,Tehran University of Medical Sciences

#### Full name of responsible person

Masud Yunesian, Vice chancellor for research

#### Street address

6th floor, Central organization of Tehran University of Medical Sciences, Keshavarz Blvd

#### City

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

### Contact

#### Name of organization / entity

School of Rehabilitation Sciences, Tehran University of Medical Sciences

#### Full name of responsible person

Nastaran Ghotbi

#### Position

PT, PhD in Physiotherapy, Associated Professor, Tehran University of Medical Sciences

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Department of Physical therapy, School of Rehabilitation, Tehran University of Medical Sciences.

**Full name of responsible person**

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**Position**

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**Other areas of specialty/work****Street address**

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**City**

Tehran

**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*