

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparing the immediate and late effects of local ankle cooling by cold spray and ice pack on balance in healthy subjects

#### Protocol summary

##### Summary

The statistical population of this research includes all companions of patients referred to physiotherapy clinics in Isfahan in 1395. By using the available sampling, among the volunteers in the study, individuals aged between eighteen and thirty will be selected according to the criteria for entering and leaving the research as participants, and after completing the consent form, they will be included in the study. Inclusion criteria include ages 18 to 30 years; BMI between 18 and 25; exclusion criteria including any pathological symptoms, fracture history, surgery, or joint diseases in the lower extremities; history of ankle ligament damage; history of sensory and motor disorder; Cold allergy including Raynaud's disease; professional athlete; visual impairment; any skin lesions; vascular problems; pathological problems of the spine; foot problems; central nervous system problems affecting balance. The exam will be conducted in a session. At the beginning of the session, after recording general information including height and weight, the length of the lower limb is measured from the anterior superior iliac spine to the ankle in the supine position. The training and exercises required for performing equilibrium tests will be provided. The modified equilibrium test of the star in three directions is then used to evaluate dynamic equilibrium and a standing on one leg with closed eyes to assess the static equilibrium on the dominant foot, and the score will be recorded for each person. The static and dynamic equilibrium test will be arranged randomly and by throwing coins. After equilibrium evaluation, randomly, for a group of participants, twenty minutes of ice bag will be used on the dominant ankle and for the other group the cold spray will be used for five seconds with a distance of 30 cm and an angle of 30 degrees from the dominant ankle surface. Immediately after applying the cold, star's equilibrium test and a stand on one leg with closed eyes test on the dominant leg will be done and the scores will be recorded. The Star test and

the stand on one leg with closed eyes test will be repeated for 30 minutes and one hour after cold application in both methods and the results will be recorded. In this study, blindness was not made.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102930544N1**

Registration date: **2017-08-04, 1396/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-04, 1396/05/13

##### Registrant information

##### Name

Shabnam Talebi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3662 1350

##### Email address

talebishabnam62@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-10-31, 1395/08/10

##### Expected recruitment end date

2017-05-22, 1396/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the immediate and late effects of local ankle cooling by cold spray and ice pack on balance in healthy subjects

**Public title**

Comparing the immediate and late effects of local ankle cooling by cold spray and ice pack on balance in healthy subjects

**Purpose**

Other

**Inclusion/Exclusion criteria**

Inclusion criteria : age:18-30 BMI: 18-25 Exclusion criteria: pathological symptoms, fracture history, surgery, or joint diseases in the lower extremities; Ankle ligaments injury; Sensory and motor disorders; Cold sensitivity and synovial disease; Professional athletes; Cutaneous injury or disease; Vascular problem; Spinal column pathologic problem; Foot problem; Balance disorder

**Age**

From **18 years** old to **30 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezarjarib St , Isfahan

**City**

Isfahan

**Postal code****Approval date**

2016-10-06, 1395/07/15

**Ethics committee reference number**

1395.7.395527

**Health conditions studied****1****Description of health condition studied**

Balance

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Static balance

**Timepoint**

Immediately after intervention, thirty minutes and one hour after intervention

**Method of measurement**

Stand on one leg with closed eyes

**2****Description**

Dynamic balance

**Timepoint**

Immediately after intervention, thirty minutes and one hour after intervention

**Method of measurement**

Y test

**Secondary outcomes****1****Description**

The skin temperature

**Timepoint**

Immediately, thirty minutes and one hour after intervention

**Method of measurement**

Skin Thermometer

**Intervention groups****1****Description**

Group one Apply 20 minutes of ice bag on ankle

**Category**

Other

## 2

### Description

Group two Apply cold spray for 5 seconds on ankle

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taskin Physiotherapy Center

##### Full name of responsible person

Shabnam Talebi

##### Street address

Bahonar St., Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

##### Full name of responsible person

Mehdi Nematbakhsh

##### Street address

Hezarjarib St., Isfahan

##### City

Isfahan

#### 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, Isfahan 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

Isfahan University of Medical Sciences

##### Full name of responsible person

Mojtaba Heshmati poor

#### Position

Faculty member

#### Other areas of specialty/work

#### Street address

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#### Fax

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#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Mojtaba Heshmati poor

##### Position

Masters

##### Other areas of specialty/work

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##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Shabnam Talebi

##### Position

Masters student

##### Other areas of specialty/work

##### Street address

Sheikh Sadoogh shomali St, Isfahan

##### City

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##### Postal code

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##### Email

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##### Web page 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*