

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison effect of Mulligan tape and Kinesiotape on the neuromuscular control in response to unpredictable perturbation in patients with chronic ankle instability

#### Protocol summary

##### Study aim

Comparison of the effect of Mulligan type and Kinesio tape on neuromuscular control of ankle muscles in response to sudden disturbance in patients with chronic ankle instability

##### Design

A clinical trial with a control group, cross-over, randomized study. 23 patients are enrolled in the study. Each subject receives three treatments (control, Malignant type, and Kinesiotape), in a random order.

##### Settings and conduct

First, the evaluation is done and then the participants receive the treatment (control, malignant type, or Kinesio tape) for 24 hours. The assessment is then performed again, after which the participants receive other crossover treatments. Our study will be single-blind so that the data analysis will be done by another person. The study site will be in the school of Rehabilitation, Tehran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 35 years old The initial sprain must have occurred at least 12 months before enrollment in the study At least 1 ankle sprain was associated with inflammatory symptoms Exclusion criteria: A history of previous surgery to the musculoskeletal structures in either lower extremity

##### Intervention groups

1. Kinesio tape group 2. Mulligan tape group 3. Control

##### Main outcome variables

Time of short and medium latency response The amplitude of short and medium latency response

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210224050481N1**

Registration date: **2021-07-03, 1400/04/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-03, 1400/04/12**

Update count: **0**

##### Registration date

2021-07-03, 1400/04/12

##### Registrant information

###### Name

Roghaye Shadegani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7729 8015

###### Email address

roghaye\_h92@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2021-10-22, 1400/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of Mulligan tape and Kinesiotape on the neuromuscular control in response to unpredictable perturbation in patients with chronic ankle instability

## Public title

Comparison effect of Mulligan tape and Kinesiotape in patients with chronic ankle instability

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

18 to 35 years old The initial sprain must have occurred at least 12months prior to the study enrollment At least 1 ankle sprain was associated with inflammatory symptoms Having "giving way" or "feeling of instability. At least 1 ankle sprain resulted in at least 1 interrupted day of desired physical activity The most recent injury must have occurred more than 3 months before enrollment in the study. Having unilateral ankle sprain

### Exclusion criteria:

A history of previous surgery to the musculoskeletal structures in either lower extremity A history of fracture in either lower extremity requiring realignment Acute injury to the musculoskeletal structures of other joints of the lower extremity in the previous 3 months that affected joint integrity and function and resulted in at least 1 day of interrupted desired physical activity

## Age

From **18 years** old to **35 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **23**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Each subject receives all treatments (control, Malignant type, and Kinesiotape), in a random order. Simple randomization is done by sealed envelopes containing the treatment allocation.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Data collection will be done by the lead researcher and data analysis will be done by another person in order to be a single blind study.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

#### Street address

District 12, Enghelab St, Pich-e-Shemiran. Tehran Town

#### City

Tehran

#### Province

Tehran

#### Postal code

1148956111

#### Approval date

2021-02-20, 1399/12/02

#### Ethics committee reference number

IR.TUMS.FNM.REC.1399.223

## Health conditions studied

## 1

### Description of health condition studied

Chronic Ankle Instability

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

## 1

### Description

Time of short and medium latency response

#### Timepoint

Before and 24 hours after treatment

#### Method of measurement

The time of medium and short latency response will be calculated based on a Baseline-Based Method. Thus, the time of short latency response is considered as a moment that Electromyography (EMG) activity will higher than the mean value plus 3 standard deviations (SD) and must be above the threshold at least 10 ms. The time of medium latency response is considered as a moment that Electromyography (EMG) activity will higher than the mean value plus 3 standard deviations (SD) and Stay above the threshold at least 20 ms. The mean value was assessed in the first 20 ms after the beginning of the short latency response.

## 2

### Description

Amplitude of short and medium latency response

#### Timepoint

Before and 24 hours after treatment

#### Method of measurement

The amplitude of medium and short latency response will be calculated based on a Root Mean Square. Two 20 millisecond (ms) windows were defined. The first window started at the onset of the short latency response and

the second window started 30 ms later after the onset of the short latency response. The 10 ms division between the two windows.

## Secondary outcomes

### 1

#### Description

Antagonist co-activation during short and medium latency response

#### Timepoint

Before and 24 hours after treatment

#### Method of measurement

The Antagonist Co-activation for Peroneus and Tibialis Anterior Muscles The Antagonist Co-activation for Tibialis Anterior and soleus Muscles we will measure with formula

## Intervention groups

### 1

#### Description

First intervention group (Kinesio Tape group)- The kinesio type is placed on the Proneus Langus and Brevis and the anterior tibialis muscles for 24 hours with a tension of 35%  $\pm$  25% from the origin to insertion of the muscle.

#### Category

Rehabilitation

### 2

#### Description

Second intervention group (Mulligan tape)-A painless posterior, lateral and superior glide is applied to the fibula in the inferior tibiofibular joint and then the tip is closed around the ankle.

#### Category

Rehabilitation

### 3

#### Description

Control group (Without Tape)- In this group, the patient does not receive treatment.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Rehabilitation

##### Full name of responsible person

Roghaye Shadegani

##### Street address

School of Rehabilitation, Pich-e-Shemiran, Enghelab St, Tehran,

##### City

Tehran

##### Province

Tehran

##### Postal code

1148956111

##### Phone

+98 21 7753 5132

##### Email

rehabilitation@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Roya Khanmohammadi

##### Street address

Rehabilitation school, Pich-e-Sheimiran, Enghelab St, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1148956111

##### Phone

+98 21 7753 5132

##### Email

rehabilitation@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Roghaye Shadegani

##### Position

Master student

##### Latest degree

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

No. 29, West 198 St, Bagheri Highway, Tehranpars

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**Postal code**

1686937411

**Phone**

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**Email**

Roghaye\_h92@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Roghaye Shadegani

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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

Tehran University of Medical Sciences

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Master student

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available