Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating effects of kinesio tape on spasticity in para-athletes with hypertonia

Protocol summary

Study aim
This study aims to assess the impact of Kinesio taping on lower limb spasticity among Paralympic athletes.

Design
A randomized, triple-blind, parallel groups controlled trial on 40 patients. Opaque envelopes will be utilized for the randomization.

Settings and conduct
Study location: Physiotherapy clinics of the Rehabilitation Faculty, Tehran University of Medical Sciences; Study population: Paralympic athletes with spasticity; Study design: Patients, assessor, statistical analyst.

Participants/Inclusion and exclusion criteria
Inclusion criteria: para-athletes with lower limb spasticity in their lower limbs ability to speak in Persian 18 years or older exercise for at least six hours per week Exclusion criteria: receiving other rehabilitation treatments other musculoskeletal disabilities using any medications affecting spasticity complete paraplegia

Intervention groups
Intervention group: Kinesiotape on the quadriceps and gastrocnemius muscles for two weeks. Control group: Kinesiotape without stretch on the quadriceps and gastrocnemius muscles for two weeks.

Main outcome variables
The level of spasticity in the quadriceps and gastrocnemius muscles using the Modified Modified Ashworth Scale (MMAS); the range of motion of the ankle and knee, balance.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210811052141N3**
Registration date: **2024-05-24, 1403/03/04**
Registration timing: **registered_while_recruiting**
Last update: **2024-05-24, 1403/03/04**
Update count: **0**

Registration date
2024-05-24, 1403/03/04

Registrant information

Name
Amin Nakhostin-Ansari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7797 1942

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating effects of kinesio tape on spasticity in para-athletes with hypertonia

Public title
Kinesio tape in para-athletes with hypertonia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
para-athletes with lower limb spasticity in their lower

limbs ability to speak in Persian 18 years or older exercise for at least six hours per week

Exclusion criteria:

receiving other rehabilitation treatments other musculoskeletal disabilities using any medications affecting spasticity complete paraplegia

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Intervention and placebo labels will be written on paper and placed inside 40 identical envelopes. The secretary will then randomly select an envelope from a box to assign each participant to a group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The assessor and para-athletes will not know which type of intervention is being applied. Additionally, the data analyst will not be informed about the treatment details. The tape used will be of similar shape for both groups, with the distinction that it will not be stretched in the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Neuroscience Institute

Street address

Neuroscience Institute, Imam Khomeini Hospital Complex, Gharib street

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۳۹

Approval date

2021-06-01, 1400/03/11

Ethics committee reference number

IR.TUMS.NI.REC.1400.026

Health conditions studied

1

Description of health condition studied

Spasticity in Paralympic athletes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Spasticity

Timepoint

Before intervention, immediately after intervention, 4 week after intervention

Method of measurement

Modified Modified Ashworth Scale

2

Description

Balance

Timepoint

Before intervention, immediately after intervention, 4 week after intervention

Method of measurement

Brief-BESTest

3

Description

Range of motion

Timepoint

Before intervention, immediately after intervention, 4 week after intervention

Method of measurement

goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Kinesio tape will be applied on the gastrocnemius and quadriceps muscle for two weeks and kinesio tapes will be stretched 25% of their original length

Category

Rehabilitation

2

Description
Control group: Kinesio tape will be applied on the gastrocnemius and quadriceps muscle for two weeks and kinesio tapes will not be stretched.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation, Tehran University of Medical Sciences
Full name of responsible person
Noureddin Nakhostin Ansari
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School of Rehabilitation; Pich-e-Shemiran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
51539
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
Noureddin Nakhostin Ansari
Position
Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data will become available upon deidentification.
When the data will become available and for how long
The data will be available upon the completion of the study.
To whom data/document is available
Other Researchers
Under which criteria data/document could be used
Data may be used for research purposes.
From where data/document is obtainable
Applicants should email prof. Nakhostin Ansari at nakhostin@tums.ac.ir
What processes are involved for a request to access data/document
The data will be will be available from the corresponding author upon reasonable request.
Comments