Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

Investigating the Immediate Effects of Kinesio Taping on Anterior Cruciate Ligament Forces in Athletes AfterACL Reconstruction Using Musculoskeletal Modeling

Protocol summary

Study aim

To investigate the immediate effect of Kinesiotaping on anterior cruciate ligament force in athletes following anterior cruciate ligament reconstruction using musculoskeletal modeling.

Design

A randomized, controlled, two-arm, parallel-group clinical trial with 1:1 allocation, including a 12-participant pilot study. Block randomization with concealed allocation will be used, with blinding of the biomechanical assessor and statistical analyst. The trial is non-pharmacological, with no applicable phase.

Settings and conduct

The study will be conducted at the orthopedics and physiotherapy clinics of Shahid Beheshti Hospital in Babol and the biomechanics laboratory of Babol University of Medical Sciences. Participants will be randomly assigned to receive either Kinesio Taping or sham taping and will perform movement tests while data from force plates and inertial measurement units are simultaneously recorded. The data will be analyzed using musculoskeletal modeling to estimate anterior cruciate ligament force. The biomechanical assessor and the statistical analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female athletes aged 18 to 40 years, with a history of unilateral anterior cruciate ligament reconstruction performed at least 6 months previously, regular sports activity, and no significant functional limitation of the lower extremity. Exclusion criteria: A history of previous knee injury or surgery, significant concomitant knee injuries or injuries limiting function, severe knee pain or instability, knee locking or swelling, and neurological or systemic disorders affecting motor function.

Intervention groups

Kinesio taping group, Sham taping group

Main outcome variables

Peak anterior cruciate ligament force during the landing phase, normalized to body weight (N/kg); knee flexion angle at initial contact; peak knee flexion angle; knee valgus/Varus angle; internal/external tibial rotation; peak vertical ground reaction force; knee joint moment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260913071033N1**
Registration date: **2026-09-15, 1405/06/24**
Registration timing: **prospective**

Last update: **2026-09-15, 1405/06/24**
Update count: **0**

Registration date

2026-09-15, 1405/06/24

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2028-02-20, 1406/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Immediate Effects of Kinesio Taping on Anterior Cruciate Ligament Forces in Athletes AfterACL Reconstruction Using Musculoskeletal Modeling

Public title

Investigation of the effect of kinesio-taping on the force exerted on the anterior cruciate ligament.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 40 years Being physically active, defined as engaging in regular sports activities at least 3 sessions per week, with each session lasting at least 30 minutes History of unilateral anterior cruciate ligament (ACL) reconstruction surgery At least 6 months elapsed since anterior cruciate ligament reconstruction surgery Isolated anterior cruciate ligament tear, without concomitant injury to other major knee ligaments Having undergone ACL reconstruction using the same surgical technique with an autologous semitendinosus and gracilis tendon graft Ability to independently perform all functional tests included in the study Full active range of motion of the knee joint, defined as 0° extension and at least 130° flexion or equivalent to the contralateral limb No functional limitation of the lower extremity at the time of assessment No knee joint locking at the time of study enrollment No visible joint effusion or swelling at the time of assessment Providing informed consent to participate in the study

Exclusion criteria:

Presence of severe concomitant knee injuries, including injuries to the medial collateral ligament (MCL), lateral collateral ligament (LCL), posterior cruciate ligament (PCL), or other significant structural injuries History of previous injury or surgery in either knee Presence of concomitant meniscal injury requiring functional restrictions or a different rehabilitation protocol Presence of neurological disorders affecting motor control and balance Presence of severe cardiovascular diseases limiting physical activity Presence of systemic or musculoskeletal diseases affecting motor function Presence of severe pain or functional knee instability during testing Development of knee joint locking or swelling during the study period Withdrawal of consent or unwillingness to continue participation in the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to either the mechanical correction Kinesiotaping group or the sham taping group at the individual level, with a 1:1 allocation ratio. A permuted block randomization method with variable block sizes of 4 and 6 will be used to generate the randomization sequence. The randomization sequence will be generated by an independent statistician using random sequence generation software. No stratified or cluster randomization will be used. For allocation concealment, the randomization sequence will be placed in sequentially numbered, opaque, sealed envelopes. The envelopes will be prepared by a researcher independent of the assessment and intervention procedures. After completion of the baseline assessments for each participant, the next sequentially numbered envelope will be opened to determine the participant's group allocation. Thus, group allocation will remain concealed from the assessor and the person performing the baseline assessments until completion of the baseline assessments.

Blinding (investigator's opinion)

Single blinded

Blinding description

After receiving complete information about the study objectives, procedures, and interventions, participants will be informed that they are taking part in a clinical trial and will receive one of the two taping interventions. However, they will be blinded to the type of intervention they receive (mechanical correction Kinesiotaping or sham taping). To maintain blinding, participants will not be provided with information regarding any potential differences or superiority of either taping method. The assessor responsible for collecting and analyzing the biomechanical data will be blinded to the participants' group allocation and will not have access to information regarding the intervention group during data processing. In addition, an independent statistical analyst will be blinded to group allocation and will perform the statistical analyses without knowledge of the type of intervention received by the participants. The researcher responsible for group allocation and intervention administration will be aware of the participants' group assignments but will not participate in the assessment or analysis of the biomechanical data or in the statistical analysis. Group allocation will be performed after completion of the baseline assessments using sequentially numbered, opaque, sealed envelopes. Thus, the biomechanical assessor and statistical analyst will remain blinded to group allocation throughout the outcome assessment and data analysis procedures.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Modarresan Street, Shah Nazari Street, Mirdamad, Mother Square

City

Tehran

Province

Tehran

Postal code

۱۳۴۸۷ ۱۵۴۵۹

Approval date

2026-09-09, 1405/06/18

Ethics committee reference number

IR.IUMS.REHAB.REC.1405.028

Health conditions studied

1

Description of health condition studied

ACL reconstruction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak anterior cruciate ligament force during the landing phase will be estimated using musculoskeletal modeling in OpenSim. The peak anterior cruciate ligament force will be normalized to the participant’s body weight and reported in newtons per kilogram (N/kg). The outcome will be calculated as the mean of three valid trials of the landing task.

Timepoint

Anterior cruciate ligament force will be measured during a single session after baseline assessment and immediately following the Kinesiotaping or sham taping intervention, during the landing task.

Method of measurement

Anterior cruciate ligament force will be estimated using musculoskeletal modeling based on movement data recorded by inertial measurement units and ground reaction force data recorded by a force plate. The data will be synchronized and processed for biomechanical analysis using OpenSim software.

Secondary outcomes

1

Description

Knee flexion angle at initial ground contact, expressed in degrees, will be measured during the landing task. This variable will be calculated from the movement data recorded during the task and processed using musculoskeletal modeling.

Timepoint

During a single session, after the baseline assessment and immediately following the Kinesiotaping or sham taping intervention, during the landing task.

Method of measurement

Knee flexion angle will be calculated in degrees from movement data recorded by inertial measurement units and processed using musculoskeletal modeling in OpenSim software.

2

Description

Knee valgus or varus angle during the landing phase, expressed in degrees, will be measured.

Timepoint

During a single session, after the baseline assessment and immediately following the Kinesio taping or sham taping intervention, during the landing task.

Method of measurement

Knee valgus or varus angle will be calculated in degrees from movement data recorded by inertial measurement units and processed using biomechanical analysis and musculoskeletal modeling in OpenSim software.

3

Description

Internal or external tibial rotation angle during the landing phase, expressed in degrees, will be measured.

Timepoint

During a single session, after the baseline assessment and immediately following the Kinesiotaping or sham taping intervention, during the landing task.

Method of measurement

Internal or external tibial rotation angle will be calculated in degrees from movement data recorded by inertial measurement units and processed using biomechanical analysis and musculoskeletal modeling in OpenSim software.

4

Description

Peak vertical ground reaction force during the landing phase, expressed in newtons, will be measured.

Timepoint

During a single session, after the baseline assessment and immediately following the Kinesiotaping or sham taping intervention, during the landing task.

Method of measurement

Peak vertical ground reaction force will be recorded using a Bertec force plate at a sampling frequency of 1000 hertz and expressed in newtons.

5

Description
Peak knee joint moment during the landing phase, expressed in newton meters, will be measured.
Timepoint
During a single session, after the baseline assessment and immediately following the Kinesiotaping or sham taping intervention, during the landing task.
Method of measurement
Peak knee joint moment will be calculated in newton meters using movement data and ground reaction force data following inverse kinematics and inverse dynamics analyses in OpenSim software.

Intervention groups

1

Description
Intervention group: Participants in this group will receive sham taping. The same type of adhesive tape used in the Kinesiotaping group will be applied. The tape will be applied without therapeutic tension and without producing a mechanical correction effect on the knee. The location and application procedure will be kept as similar as possible to those used in the Kinesiotaping group; however, the mechanical correction technique will not be applied. Sham taping will be performed in a single session immediately before the movement tasks.
Category
Rehabilitation

2

Description
Control group: Participants in this group will receive sham taping. The same type of kinesiology tape used in the intervention group will be applied to the knee without applying the mechanical correction technique or therapeutic tension. The location and application procedure of the tape will be kept as similar as possible to those used in the intervention group. Sham taping will be applied in a single session immediately before the movement task.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshti babol
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
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Position

Associate 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data and biomechanical data obtained from the study, including non-identifiable demographic characteristics, primary and secondary outcome data, and processed data related to the movement tasks. Data that could directly or indirectly identify participants, identifying information, and confidential medical information will not be shared with other researchers. Shareable data will be provided only after removal or de-identification of identifying information.

When the data will become available and for how long

Access to the de-identified data will begin 6 months after publication of the primary study results and will remain available for 5 years from the date of publication of the primary results.

To whom data/document is available

Qualified researchers and members of academic or research institutions with a scientifically justified request may apply for access to the data.

Under which criteria data/document could be used

The data may be used only for scientific and research purposes related to the study and following approval of the request. The data must be used in a de-identified manner and may not be used to re-identify participants, for commercial purposes, or for purposes inconsistent with research ethics principles. Applicants must specify the research objective, proposed analyses, and procedures for maintaining data confidentiality in their request.

From where data/document is obtainable

Applicants may submit data access requests to the principal investigator through the contact information provided in the Iranian Registry of Clinical Trials. The request should include the research objective, the type of data requested, and the proposed method of data use.

What processes are involved for a request to access data/document

Upon receipt of a request, the research purpose, type of data requested, proposed use of the data, and procedures for maintaining data confidentiality will be reviewed. If the request is approved, the relevant data will be de-identified and provided to the applicant after agreement on the terms of data use. Requests will generally be reviewed within 30 business days. The time required to provide the data after approval will depend on the type and volume of data requested.

Comments