Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of kinesiotape on gait performance and fatigue in patients over 50 years old with intermittent claudication referred to Sina hospital: A single-blind randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of kinesiotape on gait performance and fatigue in patients with intermittent claudication

Design

Randomized, single blinded parallel group trial on 30 patients. The distribution of candidates will be done by block randomization and random numbers table using Random Allocation Software.

Settings and conduct

The intended intervention includes the use of kinesiotape in treatment and control groups. In treatment group, kinesiotape will be attached from the origin of the gastrocnemius muscle in two directions, towards the insertion point of this muscle on the heel bone. In the control group, a kinesiotape will be attached to the superior part of the gastrocnemius horizontally, almost perpendicular to this muscle. All stages of this study will be performed in the sports medicine department of Sina Hospital and in this study, only the data analyzer is blinded.

Participants/Inclusion and exclusion criteria

The inclusion Criteria consists of Ankle-Brachial Index <0.9, patients with symptomatic peripheral arterial disease, age over 50 years and intermittent claudication stage 2 and 3 in the Rutherford classification. The exclusion criteria consists of having critical organ ischemia, pain while resting, amputated limb, having a respiratory disease, contraindications for kinesiotape application

Intervention groups

The intended intervention includes the use of kinesiotape with therapeutic protocol (intervention group) or non-therapeutic and ineffective protocol (control group) on patients with peripheral arterial disease and intermittent claudication.

Main outcome variables

6 Minutes Walk Test (distance covered by walking in 6 minutes); Claudication Pain Distance; Claudication Pain Time ; Maximal Walking Distance (until the appearance of symptoms); Maximal Walking Time (until the appearance of symptoms) ;American Orthopedic Foot and Ankle Score (AOFAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220910055929N1**
Registration date: **2023-02-24, 1401/12/05**
Registration timing: **retrospective**

Last update: **2023-02-24, 1401/12/05**
Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Masoomeh Salahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of kinesiotape on gait performance and fatigue in patients over 50 years old with intermittent claudication referred to Sina hospital: A single-blind randomized clinical trial

Public title

Evaluation of the effect of kinesiotape on performance of patients over 50 years old with intermittent claudication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with symptomatic peripheral arterial disease Age over 50 years Intermittent claudication stage 2 and 3 in the Rutherford classification system Ankle-Brachial Index < 0.9

Exclusion criteria:

Having critical organ ischemia Pain while resting Amputated limb Having a respiratory disease Contraindications for kinesiotape application such as: deep vein thrombosis, kidney failure, congestive heart disease, infection, wound, cancer and sensitivity to kinesiotape The patient's unwillingness to cooperate

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The distribution of volunteers was done by random block method with blocks of two, three, four and six (15 places in total) and one group was named with the symbol A and the other group with the symbol B. Using the random allocation table of the "Random Allocation Software 2.0", the assignment of candidates to the positions within the blocks was done. The sample allocation ratio will be 1:1 and volunteers will be placed in two groups receiving kinesiotape therapy (A) or ineffective kinesiotype (B). Then, based on the obtained blocks and according to the order of the allocation sequence, one of two types of intervention is performed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patient and the researcher are fully aware of the type of treatment received by each patient. In the following, the collected data is provided to the analyst in raw form, but information about whether each of these data belongs to the treatment group or the control group is not provided to the analyst and in other words, in this study, the analyst will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Sina Hospital - Tehran University of Medical Sciences

Street address

Imam Khomeini St., Sina Hospital, Research Vice-Chancellor

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1401.024

Health conditions studied

1

Description of health condition studied

Peripheral Arterial Disease

ICD-10 code

I73.9

ICD-10 code description

Peripheral vascular disease, unspecified

Primary outcomes

1

Description

6 Minutes Walk Test

Timepoint

Before the intervention, immediately and 72 hours after the intervention

Method of measurement

The patient is asked to walk a distance of 30 meters as many times as possible and at the end of the sixth minute, the distance traveled is measured.

2

Description
Claudication Pain Distance
Timepoint
Before the intervention, immediately and 72 hours after the intervention
Method of measurement
It is measured based on the distance covered until the onset of pain on the treadmill

3

Description
Claudication Pain Time
Timepoint
Before the intervention, immediately and 72 hours after the intervention
Method of measurement
It is measured based on the time elapsed until the onset of pain on the treadmill

4

Description
Maximal Walking Distance
Timepoint
Before the intervention, immediately and 72 hours after the intervention
Method of measurement
It is measured based on the distance covered up to the endurance limit on the treadmill

5

Description
Maximal Walking Time
Timepoint
Before the intervention, immediately and 72 hours after the intervention
Method of measurement
Based on the time the patient has walked on the treadmill to the limit.

Secondary outcomes

1

Description
American Orthopedic Foot and Ankle Score (AOFAS) assessment: The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score is among the most commonly used instruments for measuring the outcome of treatment in patients who sustained a complex ankle or hindfoot injury. It combines a clinician-reported and a patient-reported part
Timepoint
Before the intervention, immediately and 72 hours after the intervention
Method of measurement
The American Orthopedic Foot and Ankle Score (AOFAS) has a four-point Likert scale. The total score is divided into three sub-headings, which include pain, function and alignment. A maximum score of 100 is obtained by combining patient-reported pain and function scores and physician-assessed gait (in terms of alignment).

Intervention groups

1

Description
Intervention group: In the intervention group, to attach the kinesiotape, the patient is placed on the bed in prone position and the leg will be in dorsiflexion. Then the spot is disinfected with alcohol and two strips are attached from the origin of the gastrocnemius muscle in two directions, one along the medial part of this muscle and the other along the lateral part of this muscle towards the final insertion point of this muscle on the heel bone.
Category
Treatment - Devices

2

Description
Control group: In the control group, the patient will be placed in a prone position and the foot will be placed in a neutral position (without flexion or extension) and after disinfecting the area with alcohol, a kinesiotape will be attached to the superior part of the gastrocnemius horizontally, almost perpendicular to this muscle.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Masoomeh Salahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Akbar Fotouhi

Street address

Vice chancellor for research and technology, 6th floor, Central building of Tehran University of Medical Sciences, Ghods street, Keshavarz boulevard

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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

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

Masoomeh Salahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The present study has been registered as a proposal for the thesis of sports medicine residency. The dissertation resulting from this proposal including participants' data (all data), study protocol, statistical analysis and study report (including all variables) will be provided to Tehran University of Medical Sciences and Sports Medicine Department. It should be noted that after the dissertation is approved, an article containing all the items mentioned will be published in one of the journals relevant to the research topic. It should be noted that access to detailed data that were not published in the final report or article, requires communication with the researcher in charge of the study.

When the data will become available and for how long

The present study started on 23/9/2022 and for all stages until the submission of the dissertation, a period of two years is predicted. The data obtained from this research will be presented in the form of an article after the dissertation is approved (end of 2 years) for publication. Access to the detailed data that were not published in the final report or article will be possible after the publication of the article through direct contact with the researcher in charge of the study.

To whom data/document is available

The data obtained from this research will be available to all applicants and there will be no restrictions.

Under which criteria data/document could be used

There is no restriction on the use, dissemination or processing of the data in this study, provided that correspondence is sent via email or other means to the researcher in charge of the study and the necessary permission is issued by the researcher in charge.

From where data/document is obtainable

To access the information in this study, the applicant can contact the researcher in charge of this study by e-mail or telephone.

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

The license to use the information is issued to the applicant as soon as possible after receiving and viewing the e-mail or making a phone call, and then the requested information will immediately sent to the applicant via e-mail.

Comments