Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of ankle foot orthosis tuning using wedges on lower limb joint coordination, gait kinematics and Shank-to-Vertical Angle in stroke individuals

Protocol summary

Study aim
Determining the effect of changing the heel height of the Ankle Foot orthosis on the coordination of lower limb joints, gait kinematics, and the Shank to vertical angle

Design
This study is a single-grouped interventional study on 25 stroke patient

Settings and conduct
This study will be conducted in the Motion Analysis Laboratory of the School of Rehabilitation Sciences, Iran University of Medical Sciences, on patients with chronic stroke. A custom-made orthosis will be fabricated and fitted for each participant, and the 2-minute walk test and Timed Up and Go test will be performed under different heel heights (0–25 mm in 5-mm increments) in randomized order. Kinematic gait data will be recorded using the Qualisys Motion Capture system and analyzed by an assessor blinded to the heel height condition through coded labeling.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • Ischemic stroke (≥ 6 months post-stroke) • Ability to walk independently • Age 40–66 years • Ankle spasticity ≤ 2 (Modified Ashworth Scale) • FAC ≥ 4 Exclusion Criteria: Use of medication and presence of any disease or structural condition affecting gait.

Intervention groups
In this study, individual with stroke will receive an ankle foot orthosis with heel height adjusted between 0 and 2.5 cm, and its effects on gait kinematics and lower limb motor coordination will be evaluated.

Main outcome variables
Kinematic parameters of lower limb joints, Shank to vertical angle, leg-thigh coordination pattern, TUG and 2MWT walk test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260131068709N1**
Registration date: **2026-05-30, 1405/03/09**
Registration timing: **retrospective**

Last update: **2026-05-30, 1405/03/09**
Update count: **0**

Registration date
2026-05-30, 1405/03/09

Registrant information

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Mahtab Bagheri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2026-04-21, 1405/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ankle foot orthosis tuning using wedges on lower limb joint coordination, gait kinematics and Shank-to-Vertical Angle in stroke individuals

Public title
Analyzing the effect of Ankle Foot orthosis adjustment on gait of stroke patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of ischemic hemiplegic stroke At least 6 months have elapsed since the onset of stroke Ability to stand and walk independently without assistance or the use of a cane Modified Ashworth Scale score of 2 or less at the ankle joint Age between 40 and 66 years History of only one stroke episode Motor function of the lower extremities at Brunnstrom recovery stage 5 or higher Motor function of the upper extremities at Brunnstrom recovery stage 4 or higher Walking ability based on the Functional Ambulation Category (FAC) score of 4 or higher

Exclusion criteria:
Use of medications that may interfere with walking and balance. Structural limb length discrepancy between the lower extremitie Uncontrolled diabetes mellitus or uncontrolled hypertension Uncorrected visual or hearing impairments Bilateral involvement resulting from stroke Presence of any neuromuscular or neurological disorders, such as Parkinson’s disease, cerebellar disorders, or vestibular disorders Presence of cognitive impairment Unilateral neglect

Age
From **40 years** old to **66 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Working Group/Committee, Iran University of Medical Sciences

Street address
Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences, Central Headquarters Building, Vice President for Research and Technology

City
Tehran

Province
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Approval date
2024-04-22, 1403/02/03

Ethics committee reference number
IR.IUMS.REC.1403.064

Health conditions studied

1

Description of health condition studied
stroke

ICD-10 code
164

ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
primary outcome:Intra-limb coordination pattern between the thigh and shank during gait without an ankle-foot orthosis and under seven heel height conditions of the ankle-foot orthosis in individuals with hemiparetic stroke (instantaneous measurements).

Timepoint
Outcome measurements will be conducted in a single session and performed immediately. Assessment under each study condition (different orthotic conditions) will be carried out immediately after applying the respective condition.

Method of measurement
In this study, a Qualisys Motion Capture (QMC) motion capture analyzer with five cameras will be used to calculate joint kinematics, shank to vertical angle, and the Thigh-Shank segment coordination pattern.

Secondary outcomes

1

Description
Time to complete the Time Up and Go (TUG) test without an ankle-foot orthosis and under seven ankle-foot orthosis heel-height conditions in individuals with

hemiplegic stroke (measured immediately).

Timepoint

Outcome measurements will be conducted in a single session and performed immediately. Assessment under each study condition (different orthotic conditions) will be carried out immediately after applying the respective condition.

Method of measurement

Time Up and Go test: Total time from the command to rise from the chair, walk 3 meters, turn 180°, return, and sit back down until full buttock contact with the chair is measured using a stopwatch (in seconds).

2

Description

Distance covered during the 2-Minute Walk Test without an ankle-foot orthosis and under seven ankle-foot orthosis heel-height conditions in individuals with hemiplegic stroke (measured immediately).

Timepoint

The aforementioned study outcome will be measured in a single session and in real time. Evaluation under each investigated condition (different orthotic conditions) will be performed immediately after applying that specific condition.

Method of measurement

2-Minute Walk test: Distance covered over the entire 2-minute interval is measured using a stopwatch, from the start signal until exactly 2 minutes have elapsed.

3

Description

Shank-to-vertical angle during walking without an ankle-foot orthosis and under seven ankle-foot orthosis heel-height conditions in individuals with hemiplegic stroke (measured immediately).

Timepoint

The aforementioned study outcome will be measured in a single session and in real time. Evaluation under each investigated condition (different orthotic conditions) will be performed immediately after applying that specific condition.

Method of measurement

Shank-to-vertical angle: Angle relative to the vertical axis during stance phase, specifically at mid-stance, measured using reflective markers on the shank and 3D motion analysis system.

Intervention groups

1

Description

Intervention group: In order to make an Solid ankle-foot orthosis, a mold will be taken of the affected foot in a semi-weight-bearing position. The Solid ankle-foot orthosis is custom-made with the following features: 5 mm propylene sheet, 90-degree angle at the ankle, one centimeter cut line in front of the ankles, and two Velcro straps added horizontally to the proximal orthosis and opposite the ankles at a 45-degree angle. In each condition, heel heights are adjusted from 0 to 25 mm. There are a total of 7 assessment positions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Occupational Therapy and Physiotherapy Clinic, Faculty of Rehabilitation Sciences, Iran University o

Full name of responsible person

Ghorban Taghizadeh

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Sponsors / Funding sources

1

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Full name of responsible person

Deputy for research

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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
20
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

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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