# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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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**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

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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**

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## Sponsors / Funding sources

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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