

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of biomechanically optimized ankle foot orthosis footwear combinations on the trunk and upper limb kinematics in children with cerebral palsy while walking

#### Protocol summary

##### Study aim

Studying the effects of biomechanically optimized ankle foot orthosis footwear combination on trunk and upper limb kinematics during walking in children with cerebral palsy

##### Design

Before-and-after clinical trial in the form of a case series, non-random sampling from available samples, on 10 patients

##### Settings and conduct

Each individual will undergo a motion analysis test and functional tests of one-minute walking test and Timed up and go test in three positions: barefoot, with a conventional ankle foot orthosis, and with optimized ankle foot orthosis at the Musculoskeletal Disorders Research Center, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences. The order of the tests will be random for each participant.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Spastic hemiplegia cerebral palsy, ability to walk independently without the use of an assistive device, age 5-15 years. Exclusion criteria: Flexion contracture fix more than 25 degrees of hip and knee joints, having severe ataxia or dystonia, spasticity more than 3 on the modified Ashworth scale in the upper and lower limbs, having severe communication and cognitive impairment.

##### Intervention groups

Intervention group: Ankle foot orthoses and shoes are made both conventionally and with biomechanical optimization for each patient, and a motion analysis test is performed using each. Control group: Do not receive any intervention.

##### Main outcome variables

Trunk and upper limb kinematics in walking; walking ability; dynamic balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250202064598N1**

Registration date: **2025-03-17, 1403/12/27**

Registration timing: **prospective**

Last update: **2025-03-17, 1403/12/27**

Update count: **0**

##### Registration date

2025-03-17, 1403/12/27

##### Registrant information

##### Name

Zeinab Amini kahrizsangi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5014

##### Email address

zeinab\_amini@rehab.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-04-21, 1404/02/01

##### Expected recruitment end date

2025-09-23, 1404/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effects of biomechanically optimized ankle foot orthosis footwear combinations on the trunk and upper limb kinematics in children with cerebral palsy while walking

## Public title

The effects of optimizing ankle-foot orthosis footwear combinations on the kinematics of children with cerebral palsy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Spastic hemiplegic cerebral palsy Independent walking without the use of assistive devices (gross motor function classification 1-2)

### Exclusion criteria:

Presence of fix flexion contracture more than 25 degrees of the hip and knee joints severe symptoms of ataxia or dystonia History of surgery or specific disease in the trunk, lower limbs, elbow and wrist joints within the past 6 months Spasticity greater than 3 on the modified modified Ashworth scale in the upper and lower limbs Having severe communication and cognitive impairment (having scores of 4 and 5 on the Communication function classification system) Having a score of 5 on the MACS scale in the upper limb of the affected side

## Age

From **5 years** old to **15 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **10**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

The study includes an intervention group of children with cerebral palsy, all of whom receive interventions and the immediate effects of each intervention on kinematic data are analyzed. Additionally, a healthy control group is included, which does not receive any interventions; only their normal kinematic data are recorded.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

##### Street address

Hezar Jerib Street, Isfahan University of Medical Sciences, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2025-03-10, 1403/12/20

#### Ethics committee reference number

IR.MUI.NUREMA.REC.1403.186

## Health conditions studied

### 1

#### Description of health condition studied

cerebral palsy

#### ICD-10 code

G80.2

#### ICD-10 code description

Spastic hemiplegic cerebral palsy

## Primary outcomes

### 1

#### Description

trunk kinematic during gait

#### Timepoint

At the beginning of the study and immediately after receiving the interventions

#### Method of measurement

3D gait recording and analysis system

### 2

#### Description

Upper limbs kinematic during gait

#### Timepoint

At the beginning of the study and immediately after receiving the intervention

#### Method of measurement

3D gait recording and analysis system

### 3

#### Description

Walking ability

#### Timepoint

At the beginning of the study and immediately after receiving the intervention

## Method of measurement

1 minute walking test

## 4

### Description

Dynamic balance

### Timepoint

At the beginning of the study and immediately after receiving the intervention

### Method of measurement

Timed up and go test

## Secondary outcomes

## 1

### Description

Satisfaction

### Timepoint

At the beginning of the study and immediately after receiving the intervention

### Method of measurement

Structured interview

## 2

### Description

Spatial-temporal gait parameters

### Timepoint

At the beginning of the study and immediately after receiving the intervention

### Method of measurement

3D gait recording and analysis system

## Intervention groups

## 1

### Description

Intervention group: The conventional foot and ankle orthosis is made for each patient using a 5 mm thick polypropylene sheet after taking a mold and modifying the mold. In this orthosis, the ankle will be at 90 degrees. The orthosis extends from the tips of the toes to below the knee. The orthosis incision line in the ankle area is placed one centimeter in front of the medial and lateral malleoli. If there is a difference in the length of the lower limbs, the shortening will be compensated under the orthosis. In the conventional foot and ankle orthosis, shoes with a regular PU sole are worn. After the fitting, the patient wears the orthosis and shoes, and tests are performed.

### Category

Rehabilitation

## 2

### Description

Intervention group: The optimized ankle foot orthosis is made using a 5 mm thick polypropylene sheet for each patient after taking a mold and modifying the mold. In

the optimized orthosis, the angle of the ankle in the orthosis will match the length of the gastrosoleus muscle. The orthosis extends from the tips of the toes to below the knee. The orthosis incision line in the ankle area is placed one centimeter in front of the medial and lateral ankles. If there is a difference in the length of the lower limbs, the shortening will be compensated under the orthosis. In the optimized combination, the shoe is worn with the optimized insole. After fitting, the patient wears the orthosis and shoe and tests are performed.

### Category

Rehabilitation

## 3

### Description

Control group: Without intervention

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Orthotics and Prosthetics Clinic, Faculty of Rehabilitation Sciences, Isfahan University of Medical

#### Full name of responsible person

Saeed Forghany

#### Street address

Hezar Jerib Street, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences

#### City

Isfahan

#### Province

Isfahan

#### Postal code

73461-81746

#### Phone

+98 31 3792 5096

#### Fax

+98 31 3668 7270

#### Email

tavanbakhshi@rehab.mui.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Askari

#### Street address

Hezar Jerib Street, Isfahan University of Medical Sciences, Isfahan, Iran

#### City

Isfahan

#### Province

Isfahan

**Postal code**

73461-81746

**Phone**

+98 31 3792 5096

**Fax**

+98 31 3668 7270

**Email**

askari@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Saeed forghany

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

orthotic and prosthetic

**Street address**Hezar Jerib Street, Faculty of Rehabilitation Sciences,  
Isfahan University of Medical Sciences, Isfahan**City**

Isfahan

**Province**

Isfahan

**Postal code**

73461-81746

**Phone**

+98 31 3792 5041

**Email**

Saeed\_forghany@yahoo.co.uk

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Saeed Forghany

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Orthotic and Prosthetic

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Email**

Saeed\_forghany@yahoo.co.uk

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Study information (other than personal information) will be shared with other researchers.

**When the data will become available and for how long**

Information is shared after results or data summaries are printed.

**To whom data/document is available**

Information will be shared for academic purposes only.

**Under which criteria data/document could be used**

Information will be shared for teaching and research of applicants. Dr. Forghani (responsible administrator) will review the applications.

**From where data/document is obtainable**

Individuals can request information from the designated responsible person.

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

Applications should be sent via email to Saeed\_forghany@yahoo.co.uk.

**Comments**