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)

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+98 31 3792 5014

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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
Isfehan

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
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Hezar Jerib Street, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences
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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
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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
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
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Person responsible for updating data

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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
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