Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the efficacy of newly designed hinged Ankle Foot Orthosis with solid Ankle Foot Orthosis on center of mass fluctuation in hemiplegic Cerebral Palsy patients

Protocol summary

Study aim
Comparison the efficacy of new articulated Ankle Foot Orthosis with solid Ankle Foot Orthosis on center of mass parameters in cerebral palsy hemiplegia

Design
Clinical trial without blinding and with the sample size of 25 people

Settings and conduct
3D-motion analysis was carried out on 10 meters walk away, and 3 one-way walking trials were performed under three conditions, bare foot, with subjects' own rigid AFOs and with the HP AFO. Two legs of each participant were tested separately and three successful trials were collected for each leg. To prevent fatigue between each trial, participants were asked to take 5 minute rest. changes in center of mass were calculated by employing the method of Cavana et al. In the current study, the mechanical energy was calculated based on the COM information measured and calculated from the 3D-motion analysis data.

Participants/Inclusion and exclusion criteria
We included Cerebral Palsy hemiplegia participants, who using solid Ankle Foot Orthosis, having ability to walk at independently with or without Ankle Foot Orthosis, with Gross Motion Functional Measurement (GMFM) between 1 to 2, with Plantar flexor spasticity between 1 to 2 according to Ashworth scale , having ability to perform 5 degree dorsiflexion actively or passively. People with cognitive problems, People with injection of botulism toxin in the latest 9 month, People with lower limbs fixed flexion contracture in lower limbs joints were excluded.

Intervention groups
New articulated Ankle Foot Orthosis

Main outcome variables
Mechanical energy including potential and kinetic energy, mechanical positive and negative work, joint power

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190919044818N1**
Registration date: **2023-03-18, 1401/12/27**
Registration timing: **prospective**

Last update: **2023-03-18, 1401/12/27**
Update count: **0**

Registration date
2023-03-18, 1401/12/27

Registrant information

Name
Ensieh Pourhosaingholi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4480 3255

Email address
ensiehpmd@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the efficacy of newly designed hinged Ankle Foot Orthosis with solid Ankle Foot Orthosis on center of mass fluctuation in hemiplegic Cerebral Palsy patients

Public title
Efficacy of Ankle Foot Orthosis on center of mass
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Using solid Ankle Foot Orthosis Ability to walk at independently with or without Ankle Foot Orthosis Gross Motion Functional Measurement (GMFM) between 1 to 2 Plantar flexor spasticity between 1 to 2 according to Ashworth scale Ability to perform 5 degree dorsiflexion actively or passively
Exclusion criteria:
People with cognitive problems People with Botulism toxin injection in recent 9 month People with fixed contracture in lower limbs joints
Age
From **18 years** old to **55 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
Ethical Commtee of Hamadan University of Medical Science
Street address
Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Hamadan University of Medical Sciences Shahid Fahmideh Aven.., Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
6517838736
Approval date
2023-02-21, 1401/12/02
Ethics committee reference number
IR.UMSHA.REC.1401.1006

Health conditions studied

1

Description of health condition studied
cerebral palsy
ICD-10 code
G80
ICD-10 code description
cerebral palsy

Primary outcomes

1

Description
Mechanical energy including potential and kinetic
Timepoint
Before and immediately after intervention
Method of measurement
Motion analysis and force plate

2

Description
Mechanical positive and negative work
Timepoint
Before and immediately after intervention
Method of measurement
Motion analysis and force plate

3

Description
joint power
Timepoint
Before and immediately after intervention
Method of measurement
Motion analysis and force plate

Secondary outcomes

1

Description
Joint power
Timepoint
Before and immediately after intervention
Method of measurement
Motion analysis and force plate

Intervention groups

1

Description
Intervention group: Hydro Pneumatic Ankle Foot Orthosis
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
The biomechanical laboratory of the Movaghian Research Centre of Intelligent Neuro-Rehabilitation Te
Full name of responsible person
Ensieh Pourhoseingholi
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Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Hamadan University of Medical Sciences Shahid Fahmideh Aven.., Hamadan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Ensieh Pourhoseingholi
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
orthosis and prosthesis
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Ph.D.

Other areas of specialty/work
orthosis and prosthesis

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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
No - There is not a plan to make this available

Title and more details about the data/document
Bio mechanical parameters included center of mass, potential energy, kinetic energy, mechanical power

When the data will become available and for how long
Start of access period from 1403

To whom data/document is available
Researchers

Under which criteria data/document could be used
Performing more researches in health service system

From where data/document is obtainable
From E mail, Ensieh Pourhosaingholi

What processes are involved for a request to access data/document
After publication of paper,from E mail

Comments