

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ensieh Pourhoseingholi

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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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

orthosis and prosthesis

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Latest degree

Ph.D.

Other areas of specialty/work

Orthosis and Prosthesis

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Other areas of specialty/work

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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