Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Hinged AFOs with and without vibration on gait and daily function in children with spastic hemiplegic cerebral palsy

Protocol summary

Study aim

Evaluation of the synergistic effect of vibration and Hinged AFO on gait, function and spasticity of gastrosoleus muscle after one month in children with spastic hemiplegic cerebral palsy.

Design

Study groups include two groups of intervention and control. The intervention group will receive articulated AFO with vibrators and the control group will receive articulated AFO without vibrators. Not randomized. Not blinded. The sample size includes 24 people, which will be equal to 12 people in each group.

Settings and conduct

Participants will be selected from children referring to clinics of school of rehabilitation sciences (Iran University of Medical Sciences). Test conditions will be explained. The volunteers, will sign the consent form. Demographic information will be completed; the necessary assessments will then be made

Participants/Inclusion and exclusion criteria

Children with spastic hemiplegic cerebral palsy between the ages of 4 and 12 will be included.

Intervention groups

The orthosis used in this study is a Hinged AFO, which It will be adjusted according to the participants' ability to control the knee joint in the direction of dorsiflexion. The movement of the plantar flexion in this orthosis will be completely limited. The control group will receive the orthosis, but the intervention group will receive the same orthosis in combination with five coin vibrators located on the gastrosoleus muscles. These vibrators will be turned on only during walking.

Main outcome variables

Step length; Step width; Walking speed; Cadence; Ankle joint kinematic; Knee joint kinematic; Hip joint kinematic; plantar flexor spasticity; Duration of a full walking cycle; Performance; Satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048725N2**
Registration date: **2021-08-01, 1400/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-01, 1400/05/10**
Update count: **0**

Registration date

2021-08-01, 1400/05/10

Registrant information

Name

Maryam Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

jalali.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Hinged AFOs with and without vibration on gait and daily function in children with spastic hemiplegic cerebral palsy

Public title
Comparison of the effect of Hinged AFOs with and without vibration on gait and function in children with spastic hemiplegic cerebral palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with spastic hemiplegic cerebral palsy aged 4 to 12 years AFO prescribed by a medical specialist or therapist GMFCS level I to III The child is able to stand independently At least 2 weeks have passed since the previous lower limb orthosis was received At least six months have passed since the last Botox injection in the lower extremities spasticity grade based on Ashworth scale (2 and 3)
Exclusion criteria:
Any injuries or wounds at the orthosis site
Age
From **4 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medicine Sciences
Street address
Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-05-16, 1400/02/26
Ethics committee reference number
IR.IUMS.REC.1400.171

Health conditions studied

1

Description of health condition studied
Spastic hemiplegic cerebral palsy
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Ankle joint kinematic
Timepoint
Before the intervention and one month after
Method of measurement
Three-dimensional motion analysis

2

Description
Knee joint kinematic
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Three-dimensional motion analysis

3

Description
Hip joint kinematic
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Three-dimensional motion analysis

4

Description
Stride length
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Three-dimensional motion analysis

5

Description

Step width

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Three-dimensional motion analysis

6

Description

Function

Timepoint

Before the intervention and one month after the intervention and two weeks after weaning of the orthosis

Method of measurement

PEDI questionnaire

7

Description

Ṡpeed of walking

Timepoint

Before the intervention and one month after the intervention

Method of measurement

120 / step length × cadence

8

Description

Cadence

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Number of steps per second

9

Description

Duration of a complete walking cycle

Timepoint

Before the intervention and one month after the intervention

Method of measurement

According to each participant's gait pattern, the initial contact is detected based on kinematic data and the time interval between two successive initial contacts will be measured.

10

Description

Spasticity of the gastrosoleus muscles

Timepoint

Before the intervention and one month after the intervention and two weeks after weaning the orthosis

Method of measurement

Ashworth Scale

11

Description

satisfaction

Timepoint

Before the intervention and one month after the intervention

Method of measurement

OPUS Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The orthosis designed for the intervention group is a hinged AFO. Based on the ability of each participant to control the knee joint, range of motion of the ankle joint in the direction of dorsiflexion will be adjusted. In fact, participants with a higher level of knee control will be able to more range of motion of dorsiflexion, and accordingly, participants who have less knee control will be able to less range of motion of the ankle . The joints are made of stainless steel with a weight of 100 grams. A joint pair will be used for each orthosis. Also, the body of the orthosis is made of polypropylene sheet with a thickness of four mm, which will be shaped based on the shape of each participant's foot. The orthosis trim line is from lower than head of fibula bony to the fingertips. It will then be connected to the participants' feet via four straps. A strap is located at the leg below the knee. One strap above the ankle and one strap below the ankle and the last strap will be on the toes. The total weight of the orthosis will be between 300 and 500 grams depending on the size of the participants' feet. This orthosis also has a vibrating system. The vibrating system consists of five 5 mm diameter Lee coil vibrators with a frequency of 60 Hz, which are located on the two muscles of gastrocnemius and soleus. The duration of treatment is one month. Participants wear orthoses for at least 8 hours each day. Vibration control will be via a floor switch so that the vibrators will be turned on by placing the heel on the ground. Due to the accurate recording of the amount of light and the number of times the vibrators are turned on, a data logger will be connected to the system to record the system data based on the duration of use during one month.

Category

Rehabilitation

2

Description

Control group: The orthosis designed for this group is a hinged AFO. Based on the ability of each participant to control the knee joint, range of motion of the ankle joint in the direction of dorsiflexion will be adjusted. In fact, participants with a higher level of knee control will be able to more range of motion of dorsiflexion, and accordingly, participants who have less knee control will be able to less range of motion of the ankle . The joints are made of stainless steel with a weight of 100 grams. A

joint pair will be used for each orthosis. Also, the body of the orthosis is made of polypropylene sheet with a thickness of four mm, which will be shaped based on the shape of each participant's foot.The orthosis trim line is from lower than head of fibula bony to the fingertips. It will then be connected to the participants' feet via four straps. A strap is located at the leg below the knee. One strap above the ankle and one strap below the ankle and the last strap will be on the toes. The duration of treatment is one month. Participants wear orthoses for at least 8 hours each day. The orthosis does not have a vibrating system for this group of participants. The total weight of the orthosis will be between 300 and 500 grams depending on the size of the participants' feet.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran University of Medical Scienses, School of Rehabilitation Sciences, Orthotics and Prosthetics De

Full name of responsible person
Maryam Jalali

Street address
Madadkaran Ave., Shahnazari St., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 0947

Email
jalali.m@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyed Abbas Motevalian

Street address
Iran University of Medical Sciences Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
14496-14535

Phone
+98 21 8670 2503

Email
research-m@iums.ac.ir

Web page address
https://vcr.iums.ac.ir/

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
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
Iran University of Medical Sciences

Full name of responsible person
Maryam Jalali

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Madadkaran Ave., Shahnazari St., Mirdamad

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 0947

Email
jalali.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Maryam Jalali

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address

Madadkaran Ave., Shahnazari St., Mirdamad

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 7124

Email
jalali.m@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Zahra Jiryae

Position
Phd candidate

Latest degree
Master

Other areas of specialty/work
Others

Street address
Madadkaran Ave., Shahnazari St., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 7124

Email
jiryaei.z@gmail.com

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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

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

Analytic Code
Not applicable

Data Dictionary
Not applicable