# 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)

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**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

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## Sponsors / Funding sources

**1**

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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

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## Person responsible for scientific inquiries

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## 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