Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Design and Clinical Evaluation of a Novel Therapeutic Exercise Device for Reducing Plantar Flexor Spasticity in Children with Hemiparetic Cerebral Palsy

Protocol summary

Study aim

This study aims to develop and clinically evaluate a therapeutic exercise device designed to reduce plantar flexor spasticity in children with spastic hemiparetic cerebral palsy.

Design

This study is a single-arm, non-randomized, pre-post interventional clinical trial conducted on 15 children aged 6–10 years with spastic hemiparetic cerebral palsy.

Settings and conduct

Study Location and Procedures: The study will be conducted at Akbar Hospital Clinic using a therapeutic exercise device designed by the Medical Engineering Research Center of Islamic Azad University, Mashhad. Eligible children will be evaluated by pediatric neurology specialists. Baseline assessments will include the Ashworth Scale and Fugl-Meyer score. Participants will undergo 20 sessions of 30-minute exercise using the device. Spasticity and functional outcomes will be measured before and after the intervention. After completing the intervention, outcomes will be re-evaluated and compared with baseline data to assess the effectiveness of the device and exercises.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Spastic hemiplegic CP Age 6–10 Minimal cognition Knee and hip motor ability No interfering treatments No other neurological/psychological disorders Exclusion Criteria: No consent

Intervention groups

Children with spastic hemiparetic cerebral palsy will receive 20 sessions of therapeutic exercise using the designed mechanical ankle training device.

Main outcome variables

Change in plantar flexor spasticity measured by the Ashworth Scale at baseline and after completion of 20 intervention sessions. Change in motor function measured by the Fugl-Meyer Assessment score at baseline and post-intervention.

General information

Reason for update

Considering the limited number of eligible patients and that most participants are referred by Pediatric Neurology specialists, we propose expanding the age range of the study participants to facilitate patient recruitment and achieve the required sample size. Therefore, the age criterion for this clinical trial will be changed from 6–10 years to 6–17 years (from the beginning of 6 years of age up to the end of 17 years of age).

Acronym

IRCT registration information

IRCT registration number: **IRCT20250825066984N1**
Registration date: **2026-02-18, 1404/11/29**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **1**

Registration date

2026-02-18, 1404/11/29

Registrant information

Name

Kosar Shabani Varaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 925 1781

Email address

shabanivk4011@mums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-03-01, 1404/12/10
Expected recruitment end date
2026-08-23, 1405/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Design and Clinical Evaluation of a Novel Therapeutic Exercise Device for Reducing Plantar Flexor Spasticity in Children with Hemiparetic Cerebral Palsy

Public title
Therapeutic Exercise Device in Children with Hemiparetic Cerebral Palsy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of spastic hemiparetic cerebral palsy confirmed by a pediatric neurologist Having at least minimal cognitive ability to follow instructions Having motor capability in the knee and hip joints No other diagnosed neurological or severe psychological disorders. Age between 6 and 10 years; Not receiving other interventions that may interfere with the study;
Exclusion criteria:
Withdrawal of consent at any stage of the study
Age
From **6 years** old to **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
This study is a single-arm, non-randomized, pre-post interventional clinical trial. Participants will be evaluated at baseline and after completion of the intervention sessions.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhhad University of Medical Sciences
Street address
Ethics Committee of Mashhad University of Medical Sciences, Mashhad University of Medical Sciences Campus, Mashhad, Khorasan Razavi, 9178195853, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9178195853
Approval date
2025-12-02, 1404/09/11
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1404.435

Health conditions studied

1

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

Primary outcomes

1

Description
Change in plantar flexor spasticity
Timepoint
Baseline and after completion of 20 intervention sessions
Method of measurement
Ashworth Scale

Secondary outcomes

1

Description
Change in motor function
Timepoint
Fugl-Meyer Assessment Score
Method of measurement
Baseline and post-intervention

Intervention groups

1

Description
Participants will receive 20 sessions of therapeutic exercise using the designed mechanical ankle training device. The child will be seated, and the affected ankle will be positioned on a movable platform providing controlled mechanical stimulation to the soleus muscle.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Hospital
Full name of responsible person
Narges Hashemi
Street address
Akbar Hospital, Shahid Kaveh Boulevard, Opposite Kaveh 14, Mashhad, Khorasan Razavi, 9177897157, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177897157
Phone
+98 912 925 1781
Fax
+98 51 3870 9201
Email
Kosarshabaniv@gmail.com
Web page address
https://akbar.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Narges Hashemi
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Khorasan Razavi, 9177948564, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Email
Kosarshabaniv@gmail.com
Web page address
https://medical.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Narges Hashemi
Position
University professor
Latest degree
Subspecialist
Other areas of specialty/work
Neuroscience
Street address
Department of Pediatrics, Qaem Hospital, Ahmad Abad Avenue, Mashhad, Khorasan Razavi, 9919991766, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9919991766
Phone
+98 51 3801 2469
Email
hashemin@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Narges Hashemi
Position
University professor
Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

Street address

Department of Pediatrics, Qaem Hospital, Ahmad Abad Avenue, Mashhad, Khorasan Razavi, 9919991766, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9919991766

Phone

+98 51 3801 2469

Email

hashemin@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Kosar Shabani Varaki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Khorasan Razavi, 9177948564, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2000

Email

Kosarshabaniv@gmail.com

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

No - There is not 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

The data are displayed after individuals have been anonymized

When the data will become available and for how long

six months after the publication of the results

To whom data/document is available

Will be available to researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

The use of the data is permitted provided that the source is properly acknowledged.

From where data/document is obtainable

dr. Hamidreza Kobravi hamidrezakobravi@gmail.com dr Shabani kosarshabaniv@gmail.com

What processes are involved for a request to access data/document

They must email the designated contacts, introduce themselves, and state their request. After the email is reviewed, the materials will be sent to them if possible. (within one month)

Comments