Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Personalized Functional Electrical Stimulation Effect on Gait in Children with Cerebral Palsy

Protocol summary

Study aim
Localization and evaluation of the effectiveness and safety of personalized neuromuscular electrical stimulation in the gait of children with cerebral palsy

Design
Participants are randomly divided into two intervention groups and one control group. In intervention group 1 (FES1) the muscle nerve is determined and in intervention group 2 (FES2) the muscles themselves are directly targeted. Therefore, for each intervention group, FES of the desired muscle group will be applied, using an FES device designed with surface electrodes.

Settings and conduct
An FES device designed with applied surface electrodes will be used. This FES device is equipped with internal and external motion sensors that detect changes in the patient's body position while walking. The various parameters of the electrical pulses produced by our FES device can be changed, which helps in individual planning of stimuli. . Patients are trained to walk on a treadmill for 30 minutes, 3 times a week for 12 weeks, using an FES machine.

Participants/Inclusion and exclusion criteria
Participants will be recruited from the orthopaedic clinic of Shariati Hospital. Patients between the ages of 9 and 18 are eligible for entry if GMFCS levels I to III are diagnosed with spastic diplegic cerebral palsy. Patients should have a droping foot of central origin. To avoid interfering with the results of other treatments, patients who have recently had surgery (within 1 year) or botulinum toxin injection (within 6 months) are not included in this study. Have been reported as patient characteristics.

Intervention groups
This study compares two personalized FES protocols during walking with conventional therapies in the control group.

Main outcome variables
Functional Electrical Stimulation Protocol; Gait Analysis; Gross Motor Function Measure (GMFM88); Ultrasonic Thickness of Muscles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210712051854N3**
Registration date: **2022-07-04, 1401/04/13**
Registration timing: **prospective**

Last update: **2022-07-04, 1401/04/13**
Update count: **0**

Registration date
2022-07-04, 1401/04/13

Registrant information

Name
Mohammad Hossein Nabian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8822 1444

Email address
dr.nabian@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Personalized Functional Electrical Stimulation Effect on Gait in Children with Cerebral Palsy

Public title
Evaluation of the effect of electrical stimulation on rehabilitation of children with cerebral palsy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diplegic spastic cerebral palsy GMFCS level I to III 9-18 years old drop foot with central origin Ability to walk for at least 15 minutes Confirmation of brain abnormalities with MRI

Exclusion criteria:
Botulinum toxin injection in the last 6 months History of surgery in the last 1 year Uncontrolled epilepsy with daily seizures

Age
From **9 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address
Building No. 1, North Door of the University, Poursina St., Ghods St., Enghelab St., Tehran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2022-05-24, 1401/03/03

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.174

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
Gait analysis

Timepoint
Before the intervention and 6 months later

Method of measurement
Performing gait analysis in Javad Mofaghian Motion Analysis Laboratory (affiliated to Sharif University)

2

Description
GROSS MOTOR FUNCTION MEASURE (GMFM88)

Timepoint
Before the intervention and 6 months later

Method of measurement
During a visit with a physical therapist and rehabilitation specialist

3

Description
Ultrasonic thickness of muscles

Timepoint
Before the intervention and 6 months later

Method of measurement
A session of Ultrasonography

Secondary outcomes

1

Description
Quality of life score (QOLS)

Timepoint
Before the intervention and 6 months later

Method of measurement
Questionnaire

Intervention groups

1

Description
Control group:
Category
Rehabilitation

2

Description
Intervention group 1: using the functional electrical stimulation device, affecting the muscle nerve for 12 weeks
Category
Rehabilitation

3

Description
Intervention group 2: Using the functional electrical stimulation device, affecting the muscles themselves for 12 weeks
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Mohammad Hossein Nabian
Street address
Dr. Shariati Research and Treatment Center, Opposite the Faculty of Economics, Jalal Al-Ahmad Intersection, North Kargar St., Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ahmad Rezaie
Street address
, Deputy of Research and Technology, Sixth Floor, Central Organization of the University, Corner of Ghods St., Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
45
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Hossein Nabian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Dr. Shariati Research and Treatment Center, Opposite the Faculty of Economics, Jalal Al-Ahmad Intersection, North Kargar St., Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
dr.nabian@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Hossein Nabian

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy, North Kargar Street

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8822 1444

Fax

Email
dr.nabian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Hossein Nabian

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy, North Kargar Street

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8822 1444

Fax

Email
dr.nabian@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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after de-identifying individuals

When the data will become available and for how long
One year after completing the study

To whom data/document is available
All researchers who intend to study on these data

Under which criteria data/document could be used
Researchers will have access to these data if they intend to cooperate with the Center of Orthopedic trans-disciplinary Applied Research (COTAR)

From where data/document is obtainable
Correspondence or contact with Center of Orthopedic trans-disciplinary Applied Research (COTAR) E-mail address: cotar.tums@gmail.com Address: Tehran, North Kargar Street, Jalal Al Ahmad Street, Shariati Hospital, Emergency Building, First Floor, Center of Orthopedic trans-disciplinary Applied Research (COTAR) Phone: 021-84902722

What processes are involved for a request to access data/document
The applicant must specify the purpose of accessing the data and the type of study he/she wants to do on them by correspondence or call.

Comments