

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 dropping 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

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

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