

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Motor Learning Induced by an Anti-gravity Locomotor Training in Children With Cerebral Palsy

Protocol summary

Summary

In this study, therapeutic effects of an anti-gravity locomotor training on central nervous system structure and function, neuromuscular properties and gait in children with cerebral palsy will be studied. 100 children with cerebral palsy will be referred to neural engineering and rehabilitation center of Noorafshar hospital from rehabilitation and medical centers. 4-14 years old hemiplegic patients with spasticity in lower extremities and also with the ability of following commands who are diagnosed by pediatric neurologists will be randomly separated to study and control groups. The study group will be trained on the anti-gravity treadmill and the control group will receive over-ground walking training by an expert occupational therapist. Each group will receive up to 1 hour of training for 3 days/week for 2 months. The anti-gravity treadmill will facilitate treadmill walking with reduced lower extremity weight bearing (up to %80), which can help patients walk voluntary and actively on the treadmill. It is expected that this systematic, intensive training result in structural changes (neuroplasticity) in central nervous system, so that the nerve conduction will be facilitated and improved in neural pathways. It is expected that this systematic, intensive training result in structural changes (neuroplasticity) in central nervous system, so that the nerve conduction will be facilitated and improved in neural pathways. As a result of this neuroplasticity, the treatment effects will be long lasting and improve the children's quality of life. In addition to evaluating the clinical changes, brain structural changes, activity level of the descending neural pathways including corticospinal tracts, neuromuscular properties, balance, and the lower limbs movement ability of the children will be quantified.

General information

Acronym

CP-PGT

IRCT registration information

IRCT registration number: **IRCT2015121625568N1**

Registration date: **2016-09-06, 1395/06/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-06, 1395/06/16

Registrant information

Name

Seyed Mohammad Mehdi Mirbagheri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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mehdi@northwestern.edu

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Red Crescent of Iran Clinical Neural Engineering Research Center in Noor-Afshar Hospital

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Motor Learning Induced by an Anti-gravity Locomotor Training in Children With Cerebral Palsy

Public title

Therapeutic Effects of an Anti-gravity Locomotor Training on Central Nervous system structure and function, Neuromuscular Properties and Gait in Children with Cerebral Palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: hemiplegic patients diagnosed by a pediatric neurologist; Spasticity in lower extremities (MAS Score >1); ability to attend training/test sessions; ability of following commands; absence of severe mental retardation; absence epilepsy, chromosomal anomaly, or genetic syndrome;. absence of severe brain structural anomaly

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

TUMS, PoorSina st., Ghods st. ,Enghelab st., tehran, Iran

City

Tehran

Postal code

Approval date

2016-04-20, 1395/02/01

Ethics committee reference number

IR.TUMS.REC.1395.2441

Health conditions studied

1

Description of health condition studied

Hemiplegic Cerebral Palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description

Fractional Anisotropy

Timepoint

Four times: once a month

Method of measurement

MRI Acquisition; Post Analysis

2

Description

Mean Diffusivity

Timepoint

Four times: once a month

Method of measurement

MRI Acquisition; Post Analysis

3

Description

Berg Balance Scale

Timepoint

Four times: once a month

Method of measurement

Clinical evaluations

4

Description

Center Of Pressure Distance

Timepoint

Four times: once a month

Method of measurement

Gait Analysis

5

Description

Stride Velocity

Timepoint

Four times: once a month

Method of measurement

Gait Analysis

6

Description

Maximum Velocity Contraction

Timepoint

Four times: once a month
Method of measurement
Isokinetic

7

Description
cranial magnetic stimulation threshold
Timepoint
Four times: once a month
Method of measurement
TMS

8

Description
H-Reflex
Timepoint
Four times: once a month
Method of measurement
EMG Device

9

Description
Tissue Elasticity
Timepoint
Four times: once a month
Method of measurement
Sonoelastography

10

Description
Velocity and Endurance
Timepoint
four times: once a month
Method of measurement
clinical evaluations

Secondary outcomes

empty

Intervention groups

1

Description
AlterG group will receive 3 days/week for 8 weeks, with up to 1 hour of training per session. In each session, the training started with no body weight support and with a minimum speed. Then, the body weight support gradually increased and the speed increased as needed based on the subject's ability and the desecration of the trainer.
Category
Rehabilitation

2

Description
The control group will receive over ground walking training by an expert occupational therapist 3 days/week

for 8 weeks, with up to 1 hour of training per session.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noorafshar hospital
Full name of responsible person
Maryam Shahrokhnia
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Children's Medical center
Full name of responsible person
Parmida Moradi Birgani
Street address
City
Tehan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
TUMS
Full name of responsible person
Seyed Mohamad Mehdi Mirbagheri
Street address
TUMS, Pour Sina St., Ghods St., Enqelab Sq.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
TUMS
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity

TUMS

Full name of responsible person

Parmida Moradii Birgani

Position

PhD student

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Full name of responsible person

Shokoofeh Parvin

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M.Sc.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty