Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Siences 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 Analaysis

5

Description
Stride Velocity

Timepoint
Four times: once a month

Method of measurement
Gait Analaysis

6

Description
Maximum Velocity Conraction

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 Endorance

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

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Person responsible for scientific inquiries

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Seyed Mohamad Mehdi Mirbagheri

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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