

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

+98 21 6405 3252

###### Email address

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

### Contact

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## Person responsible for scientific inquiries

### Contact

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Seyed Mohamad Mehdi Mirbagheri

**Position**

Post Doc

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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*