

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of anti pronation static splint on activities in 8-12 years old spastic hemiplegic cerebral palsy children

Protocol summary

Summary

How to implement the plan: This study is a clinical trial and designed to investigate the effect of anti-pronation static splint on activities in 10 spastic hemiplegic cerebral palsy children with 8-12 years old. Two groups are participated in this study; an intervention group (N=10) and a control group (N=10). The patients who have inclusion criteria: 8-12 years old spastic hemiplegic cerebral palsy children; classification of 2 and 3 Gross Motor Function Classification System (GMFCS) selected randomly from therapeutic centers of Tehran. Exclusion criteria: Non-cooperation; Patients should fill the consent form and demographic questionnaire before starting the assessments. Assessments include box and block test, passive range of motion of elbow extension, forearm supination and wrist extension with goniometry, severity of spasticity with Modified Ashworth Scale, and performance of activities with Activities Scale for Kids. Colleague of examiner does the assessments in intervention and control group (10 children) and records the data. After the preliminary assessments, patients are divided into intervention and control groups. Masters will check groups with regard to severity of spasticity, level of performance, age, gender and homogeneity. In order to make of anti-pronation static splint, patients of intervention group are introduced to the research and therapeutic hand clinic in school of rehabilitation of Tehran University of Medical Sciences. After fabrication of positive mold, pattern of splint is cropped on thermoplastic material. This material is heated and placed on the positive mold and covers forearm from distal crease of ulnar side of wrist to two-thirds of upper forearm. Dorsal side on distal head of ulna is a landmark for producing a puncture. From this point a strip passes and a ring is clinched to the end of the strip. In order to prevent of pressure on the head of ulna, the pads put inside the splint and place it on the patient forearm so that the strip starts from distal and dorsal side of wrist, passes inside of splint, stands on volar side of wrist then

passes from the ring and ends on velcro of palmar side of splint. Also another strip is prepared for stabilizing splint on forearm. Duration of therapy is 8 weeks and the splint should be used 6- 8 hours during a day. The patients are trained on how to use and keep the splint. After 8 weeks of application of splints, assessments are repeated by colleague of examiner and the results will be analyzed statistically. Examiner colleague is blinded about the patients in intervention and control groups. During the intervention time, patients in intervention and control groups benefit from conventional treatments of occupational therapy such as Neurodevelopmental Treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042717450N1**

Registration date: **2014-07-02, 1393/04/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-02, 1393/04/11

Registrant information

Name

Mehdi Abdolvahab

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 8798

Email address

mabdolvahab@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of anti pronation static splint on activities in 8-12 years old spastic hemiplegic cerebral palsy children

Public title

Study of effect of anti pronation static splint on activities in 8-12 years old spastic hemiplegic cerebral palsy children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 8-12 years old spastic hemiplegic cerebral palsy children; classification of 2 and 3 Gross Motor Function Classification System (GMFCS) exclusion criteria: Non-cooperative

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Draw

Secondary Ids

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Tehran University of Medical Sciences Ethics

Committee

Street address

Tehran University of Medical Sciences , Enghelab Av,
Tehran, Iran,

City

Tehran

Postal code**Approval date**

2014-06-09, 1393/03/19

Ethics committee reference number

93-01-32-25272-112535

Health conditions studied**1****Description of health condition studied**

spastic hemiplegic cerebral palsy

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

Primary outcomes**1****Description**

Activities Scale for Kids

Timepoint

monthly

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Function

Timepoint

Monthly

Method of measurement

Box and Block Test and Activities Scale for Kids

Intervention groups**1****Description**

Control group :conventional treatments

Category

Rehabilitation

2**Description**

Intervention group : Anti Pronation Static Splint

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Centre

Full name of responsible person

Mehdi Abdolvahab

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Uonesian

Street address

Tehran University of Medical Sciences , Enghelab Av,
Tehran, Iran,

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Mehdi Abdolvahab

Position

Msc

Other areas of specialty/work

Street address

Tehran University of Medical Sciences , Enghelab Av,
Tehran, Iran,

City

Tehran

Postal code

1148965141

Phone

+98 21 7753 8798

Fax

Email

mabdolvahab@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehdi Abdolvahab

Position

Msc

Other areas of specialty/work

Street address

Tehran University of Medical Sciences , Enghelab Av,
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City

Tehran

Postal code

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+98 21 7753 8798

Fax

Email

mabdolvahab@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Fax

+98 21 7753 8798

Email

mabdolvahab@tums.ac.ir

Web page address

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