

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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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 Masuod 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

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Person responsible for updating data

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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