

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of short thumb splint on hand function in cerebral palsy children

Protocol summary

2012-07-18, 1391/04/28

Summary

This study is a before-after clinical trial on 13 children (8 boys and 5 girls) with cerebral palsy. Children are entered into this study from special schools in Tehran. After signing the consent from parents, The participants will be recruited in this study and completed a demographic questionnaire; initial assessment includes passive range of wrist extension, palmar and radial abduction of the thumb using a goniometer, hand function in patients with box & block test that is performed by the experimenter and relevant information is recorded (the order of tests is randomly). The code is given to all patients and the assessments are performed by another examiner. After the initial assessment, patients are referred for splint construction. The splint is placed in the dominant hand thumb web space (between index finger metacarpo phalangeal and thumb inter phalangeal). Duration of splinting is 4 to 6 hours per day (outside of school hours) and 6 to 8 hours at night and for 8 weeks. Parents are recorded time use of splint in schedule every day. The parents are taught the proper use of splints, maintenance procedures and its health. After 8 weeks of splinting, the initial assessment is performed by the experimenter and results are analyzed. In the intervening period, patients receive a similar occupational therapy programs.

Registrant information

Name

Nafiseh sadat Sharifi

Name of organization / entity

Tehran university of medical science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research of Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070310179N1**

Registration date: **2012-07-18, 1391/04/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

Scientific title

The effect of short thumb splint on hand function in cerebral palsy children

Public title

The effect of short thumb splint on hand function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.8-12 years old cerebral palsy children, diagnosed according to the neurologist.

2.Border and a higher IQ (according to school records).

3.Lack of surgery experience in upper extremity, according to records or the parents 4.If there are seizures can be controlled. 5.There is at least 40 degree abduction in thumb. 6.There is up to 3 scale of modified ashworth in the dominant thumb and wrist. 7.Lack of usage of other upper limb splints at the time of the implementation. 8.Lack of usage of medication to reduce spasticity in time of the implementation. Exclusion criteria: 1.Lack of cooperation of parents and children. 2.Orthopedic injuries occurring during the intervening time.

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: **15**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research of tehran uiversity of medical science

Street address

Enghelab street -ghods street-por sina street-tehran school of medical science-school medicine-third floor-technology research center

City

Tehran

Postal code**Approval date**

2012-06-28, 1391/04/08

Ethics committee reference number

91-02-61-16980-58485

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

Cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

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

Hand function

Timepoint

before the intervention, after 2 month

Method of measurement

box & block test

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

Wrist and thumb range of motion

Timepoint

Before the intervention, after 2 month

Method of measurement

Goniometer

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

Use of short thumb splint for 8 weeks(6-8 hours per day and 4-6 hours per night)

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tavan khahan special school

Full name of responsible person**Street address****City**

Tehran

2**Recruitment center****Name of recruitment center**

Emam ali special school

Full name of responsible person**Street address****City**

Tehran

3

Recruitment center

Name of recruitment center

Haji babaiy special school

Full name of responsible person

Street address

City

Tehran

4

Recruitment center

Name of recruitment center

Kosha special school

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research of tehran university of medical science

Full name of responsible person

Dr fotohi

Street address

Enghelab street-ghods street-por sina street-school of tehran medical science- school of medicine-third floor-research center

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research of tehran university of medical science

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

Theran university of medical science

Full name of responsible person

Nafiseh sadat Sharifi

Position

student of MSc

Other areas of specialty/work

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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