Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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

2012-07-18, 1391/04/28

Registrant information

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Nafiseh sadat Sharifi
Name of organization / entity
Tehran university of medical science
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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

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 uinversity 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
Goniameter

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
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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
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Nafiseh sadat Sharifi
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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