Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of hand neoprene splinting on grip, pinch strength and hand manual dexterity, in children with cerebral palsy

Protocol summary

Summary

The aim of this study is to investigate the effectiveness of hand neoprene splinting on grip, Pinch strength and manual dexterity in children with spastic hemiplegic cerebral palsy. This study is a Quasi -experimental, non-randomized, non- placebo controlled. Twenty children with aged between 6 to 14 years old and diagnosed as a child with spastic hemiplegic by a neurologist, who meet the following inclusion criteria participated in this study. The participants would select randomly from rehabilitation centers in Hamadan city. At the beginning of the study the dynamometer (digital hand dynamometer), digital Pinch gauge will be used in order to measure grip and Pinch strength and the fine motor part of the Bruninks Oseretsky Test of Motor Proficiency Measure which measure the manual dexterity and speed will be used. An independent assessor administers the tests. All children wear a neoprene splint for 6 weeks. After the completion of treatment, the dynamometer, digital Pinch gauge and Bruninks Oseretsky Test of Motor Proficiency Measure would re-administer by the same independence assessor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110915329N1**
Registration date: **2014-05-16, 1393/02/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-16, 1393/02/26

Registrant information

Name

Sedigheh sadat Mirbagheri

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2014-05-25, 1393/03/04

Expected recruitment end date

2014-06-25, 1393/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hand neoprene splinting on grip, pinch strength and hand manual dexterity, in children with cerebral palsy

Public title

Effect of dynamic splinting on function in children with cerebral palsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1.Diagnosed with hemiplegia by neurologist 2. Be in levels 2-1 of the manual ability classification system (MACS) 3. Aged from 6 to 14 years. 4. Cooperation of the patient and family Exclusion criteria: 1. Fixed shortness or deformity that limited

necessary range of motion for this study. 2. Orthopedic surgery or pharmaceutical interventions in the last 6 months for reducing spasticity 3.Diagnosed with mental retardation or cognitive delays deficits and other impairments (seizures, visual impairment and etc.)

Age
From **6 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Hamadan University of medical sciences

Street address
Hamadan University of Medical Science, Shahid Fahmide Street, Hamadan

City
Hamadan

Postal code
65178

Approval date
2013-10-29, 1392/08/07

Ethics committee reference number
 16/35/9/2403/پ

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
Grip strength

Timepoint
Before intervention, immediate after intervention, 6 weeks after intervention

Method of measurement
Using Jamar digital hand dynamometer and Kg measure

2

Description
Pinch strength

Timepoint
Before intervention, immediate after intervention, 6 weeks after intervention

Method of measurement
Using Jamar Pinch gauge and Kg measure

3

Description
Manual dexterity

Timepoint
Before intervention, 6 weeks after intervention

Method of measurement
Bruininks-Oseretsky Test of Motor Proficiency, grade scale

Secondary outcomes

1

Description
Height

Timepoint
In first of study

Method of measurement
Meter, centimeter

2

Description
Weight

Timepoint
In first of study

Method of measurement
Weight scale/ Kg

3

Description
Body mass index (BMI)

Timepoint
In first of study

Method of measurement
Weight/(height)^2

Intervention groups

1

Description
Wearing neoprene splint in intervention group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Sedigheh Sadat Mirbagheri
Street address
Department of Occupational therapy, Farshchian Hospital, Mirzade Eshghi Street, Hamadan
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Hamadan

2

Recruitment center
Name of recruitment center
Sheikhoraeis center of therapeutic educational
Full name of responsible person
Sedigheh Sadat Mirbagheri
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Sheikhoraeis center of Therapeutic educational, Khaje Rashid Street, Hamadan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeed Bashirian
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Vice chancellor for research, University of Medical Sciences, Shahid Fahmide street, Hamadan.
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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, Hamadan 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
Hamadan University of Medical Sciences
Full name of responsible person
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Position
Faculty of rehabilitation /MSc of occupation therapy.
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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