

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Iran (Islamic Republic of)

Phone

+98 81 1838 1572

Email address

s.mirbagheri@umsha.ac.ir

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

City

Hamadan

2

Recruitment center

Name of recruitment center

Sheikhoraais center of therapeutic educational

Full name of responsible person

Sedigheh Sadat Mirbagheri

Street address

Sheikhoraais center of Therapeutic educational, Khaje Rashid Street, Hamadan

City

Hamadan

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

Street address

Vice chancellor for research, University of Medical Sciences, Shahid Fahmide street, Hamadan.

City

Hamadan

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

Soraya Gharbaghi

Position

Faculty of rehabilitation /MSc of occupation therapy.

Other areas of specialty/work

Street address

Occupational therapy department, faculty of rehabilitation, Hamadan university of Medical Sciences, Hamadan.

City

Hamadan

Postal code

Phone

+98 81 1838 1572

Fax

Email

gharebaghy_ot@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rehabilitation faculty, Hamadan university of Medical Sciences

Full name of responsible person

Sedigheh Sadat Mirbagheri

Position

MSc of Orthoses and Prosthetics

Other areas of specialty/work

Street address

Occupational therapy department, Rehabilitation Faculty, Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Postal code

Phone

+98 81 1838 1572

Fax

Email

smirbagheri110@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences.

Full name of responsible person

Sedigheh Sadat Mirbagheri

Position

faculty/ MSC

Other areas of specialty/work**Street address**

Department of Occupational therapy, Rehabilitation
Faculty, Hamadan University of Medical Sciences,
Shahid Fahmide St., Hamadan

City

Hamadan

Postal code**Phone**

+98 81 1838 1571

Fax**Email****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