

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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)<sup>2</sup>

## 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

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smirbagheri110@gmail.com

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## 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*