

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison the effect of oral motor stimulations on feeding function in the children with spastic cerebral palsy by medical and family centered approach

Protocol summary

Summary

The object of this study is Comparison the effect of oral motor stimulations on feeding function in the children with spastic cerebral palsy by medical and family centered approach. Design: The population under study is all of the 2 to 8 years old children with cerebral palsy at the city of Arak. group: The children under clinician management and the children under family management. Sample size: 40 children.

Randomization: The items were selected by simple randomization. The inclusion criteria include: Diagnosis of Spastic cerebral palsy children by neurologist. spastic CP children 8-2 years. Children obtain score 3-5 from GMFCS-E & R scale. Parent have consent for children's participation in the study. the exclusion criteria include: Existence and proof intractable seizures in children. Existence mouth anomalies such as cleft palate in children at the time of project. The management was oral motor stimulation. Study time was 1 month. Outcomes studied was increasing swallowing skills of patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060828345N1**

Registration date: **2016-06-29, 1395/04/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-29, 1395/04/09

Registrant information

Name

Abdolreza Yavari

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral motor stimulations on feeding function in the children with spastic cerebral palsy by medical and family centered approach

Public title

The effect of oral motor stimulations on feeding function

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria include: Diagnosis of spastic cerebral palsy children by neurologist; Spastic CP children 8-2 years; Children obtain score 3-5 from

GMFCS-E & R scale; Parent have consent for children s participation in the study. The exclusion criteria include: Existence and proof intreatable seizures in children; Existence mouth Anomalies such as cleft palate in children at the time of project.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

N/A

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Arak. Sardasht, Arak University of Medical Sciences

City

Arak

Postal code

3848176941

Approval date

2015-07-11, 1394/04/20

Ethics committee reference number

IR.ARAKMU.REC.1394.74

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

spastic cerebral palsy

ICD-10 code

G80,G81,G8

ICD-10 code description

heredity spastic paraplegia

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

feeding function

Timepoint

pre and post management

Method of measurement

Oral motor assessment scale

Secondary outcomes

empty

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

On the children that were selected ,oral -motor stimulation approach for 15 minutes a day, 3 days a week, for 12 sessions was done by therapist.

Category

Other

2**Description**

Intervention group 1: On the children that were selected ,oral -motor stimulation approach for 15 minutes a day, 3 days a week, for 12 sessions was done by trained family

Category

Other

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

Tolue Rehabilitation Clinic

Full name of responsible person

Doctor Hamid Dalvand- ,lThe head of Department of Occupational Therapy

Street address

Alamolhoda street- pastor avenue- Park entrance

City

arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Arak University of Medical sciences

Full name of responsible person

Dr Mohamad Rafie

Street address

Sardasht, Basij Square, Arak University of Medical

sciences
City
 Arak
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 of Arak 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
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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