Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 studty 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 prooof intreatable 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)
Phone
+98 863685006
Email address
a.yavari@arakmu.ac.ir

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 prooof 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- ،IThe 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
Rehabilitation College

Full name of responsible person
Akram Valizade

Position
Mastery Science/ Faculity Member

Other areas of specialty/work

Street address
Mostafa Street, Golestan Avenue, Rehabilitation College

City
Arak

Postal code

Phone
+98 86 3368 5006

Fax

Email
akramvalizadeh59@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rehabilitation College

Full name of responsible person
Dr Hamid Dalvand

Position
PHD

Other areas of specialty/work

Street address
Mostafa Street, Golestan Avenue, Rehabilitation College

City
Arak

Postal code

Phone
+98 86 3368 5006

Fax

Email
hamiddalvand@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Rehabilitation College

Full name of responsible person
Abdolreza Yavari

Position
Mastery science/ Faculity Member

Other areas of specialty/work

Street address
Mostafa Street, Golestan Avenue, Rehabilitation College

City
Arak

Postal code

Phone
+98 86 3368 5006

Fax

Email
abdolrezayavari@yahoo.com

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