Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effect of two treatment methods of polyethylene glycol with Motilium and polyethylene glycol with placebo in the treatment of chronic constipation in children with cerebral palsy

Protocol summary

Study aim

Comparison of the effect of two method of Polyethylene Glycol with Motilium and Polyethylene Glycol alone with Placebo in treatment of chronic Constipation in children with cerebral palsy.

Design

This study is a double-blinded clinical trial. The study population will be included all children with chronic cerebral palsy who referred to Mohammad Kermanshahi hospital of Kermanshah. 42 eligible patients will be selected conveniently and randomly will be assigned to two intervention and control groups.

Settings and conduct

This study will be conducted in Mohammad Kermanshahi hospital of Kermanshah is double-blinded one, in this way that participants and clinical care providers are unaware of the allocation of intervention and control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with cerebral palsy suffer from chronic constipation; Patients with chronic constipation who have not responded to usual treatments Exclusion criteria: Children with cardiovascular problems based on E.C.G approval by a pediatric cardiologist

Intervention groups

The intervention group will receive polyethylene glycol with a dosage of 4.0 mg/kg with 0.2 mg/kg of Motilium three times a day for two weeks. The second intervention group will receive 4.0 mg/kg of polyethylene glycol with 0.2 mg/kg of placebo syrup (containing distilled water) once a day for two weeks.

Main outcome variables

Chronic constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N126**
Registration date: **2019-06-24, 1398/04/03**
Registration timing: **prospective**

Last update: **2019-06-24, 1398/04/03**
Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two treatment methods of polyethylene glycol with Motilium and polyethylene glycol with placebo in the treatment of chronic constipation in children with cerebral palsy

Public title

Comparison of the effect of two treatment methods in the treatment of chronic constipation in children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with cerebral palsy suffer from chronic constipation Patients with chronic constipation who have not responded to usual treatments

Exclusion criteria:

Children with cardiovascular problems based on E.C.G approval by a pediatric cardiologist

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the clinical carers and participate will be blinded to the allocation of study groups to intervention and experimental groups. assigned to assign the study groups. In this way that clinical carers and participate are unaware of coding and allocation of intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

ir.kums.rec.1398.067

Health conditions studied

1

Description of health condition studied

chronic constipation

ICD-10 code

K92.9

ICD-10 code description

Disease of digestive system, unspecified

Primary outcomes

1

Description

Chronic constipation

Timepoint

Two weeks after the end of the study

Method of measurement

Asking the patients and abdominal examination

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive polyethylene glycol with a dosage of 4.0 mg/kg with 0.2 mg/kg of Motilium three times a day.

Category

Treatment - Drugs

2

Description

The second intervention group will receive 4.0 mg/kg of polyethylene glycol with 0.2 mg/kg of placebo syrup (containing distilled water) once a day .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mohammad Kermanshahi Hospital
Full name of responsible person
Masoud Norouzi
Street address
Crossroads of Helal Ahmar, Mohammad Kermanshahi Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
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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
Kermanshah University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Masoud Norouzi
Position
Resident of children
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The main outcomes of the study will be shared.

When the data will become available and for how long
3 months

To whom data/document is available
If requested, results will be made available to other academic researchers

Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable
To receive the documentation, email send for update manager

What processes are involved for a request to access data/document
En In a 90-day period, the documents will be sent e-mail

Comments