Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison Oral paraffin and Polyethylene Glycol (PEG) in treatment of children with chronic functional constipation.

Protocol summary

Summary

This study is a randomized double blind trial that evaluates oral Paraffin and Polyethylene Glycol (PEG) in treatment of children with chronic functional constipation. Inclusion criteria include: all children aged 2 to 12 years with chronic functional constipation according to Rome III diagnostic criteria. Exclusion criteria include: have an organic constipation, gastrointestinal surgery and history of drug use. The sample size was calculated 160 and the study population was children aged 2-12 years with chronic functional constipation that referred to gastroenterology clinic at Mousavi Hospital in Zanjan. The patients randomly were divided into two groups. The first group was given PEG solution with dose 1 cc/kg/day (equivalent 0.8 gr/kg/day of powdered PEG) orally in two divided doses for 6 months and the second group was given Paraffin solution with dose 1 cc/kg/day orally in two divided doses for 6 months. The children were followed up once a week for first month and then monthly up to 6 months. On follow up period the therapeutic response such the number of defecation per week, stool consistency, rectal bleeding, painful defecation, fecal incontinence (Encopresis), abdominal pain and adverse effects were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091618971N2**
Registration date: **2014-10-01, 1393/07/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-01, 1393/07/09

Registrant information

Name
Kambiz Eftekhari
Name of organization / entity
Tehran University of Medical Science
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Recruitment status

Recruitment complete

Funding source

The research department of Zanjan University of Medical Sciences.

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Oral paraffin and Polyethylene Glycol (PEG) in treatment of children with chronic functional constipation.

Public title

Compare the treatment of constipation in children with paraffin and polyethylene glycol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: all children aged 2 to 12 years with chronic functional constipation according to Rome III

diagnostic criteria. Exclusion criteria include: have an organic constipation such as Hirschsprung's disease; hyporthyroidism; cardiac; renal and neurologic disorders; history of gastrointestinal surgery and drug use especially anticonvulsants; sedatives and antidepressants.

Age
From **2 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zanjan University of Medical Science

Street address
Zanjan

City
Zanjan

Postal code

Approval date
2013-07-13, 1392/04/22

Ethics committee reference number
ZUMS.REC.1392.81

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.9

ICD-10 code description
Functional intestinal disorder, unspecified

Primary outcomes

1

Description
The number of bowel movements per week

Timepoint
Once a week during the first month, then every month until 6 months

Method of measurement
History

2

Description
Stool consistency

Timepoint
Once a week during the first month, then every month until 6 months

Method of measurement
History

3

Description
Painful defecation

Timepoint
Once a week during the first month, then every month until 6 months

Method of measurement
History

Secondary outcomes

1

Description
Rectal bleeding

Timepoint
Once a week during the first month, then every month until 6 months

Method of measurement
History

2

Description
Fecal incontinence

Timepoint
Once a week during the first month, then every month until 6 months

Method of measurement
History

3

Description
Abdominal pain

Timepoint
Once a week during the first month, then every month until 6 months

Method of measurement
History

4

Description
The side effects of treatment
Timepoint
Once a week during the first month, then every month until 6 months
Method of measurement
History

Intervention groups

1

Description
The first group was given PEG solution with dose 1 cc/kg/day (equivalent 0.8 gr/kg/day of powdered PEG) orally in two divided doses for 6 months.
Category
Treatment - Drugs

2

Description
The second group was given Paraffin solution with dose 1 cc/kg/day orally in two divided doses for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mousavi Hospital
Full name of responsible person
Kambiz Eftekhari
Street address
Pediatric ward, Mousavi Hospital, Ghavazangh Street, Zanjan
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Science
Full name of responsible person
research department of Zanjan University of Medical Sciences, Dr Aliraza Bighlari
Street address
Zanjan University of Medical Science, Zanjan
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Science
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
Zanjan University of Medical Science
Full name of responsible person
Kambiz Eftekhari
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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