

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 7301 3000

Email address

k-eftekhari@sina.tums.ac.ir

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; hypothyroidism; 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, Zanzan

City

Zanzan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Science

Full name of responsible person

research department of Zanzan University of Medical Sciences, Dr Aliraza Bighlari

Street address

Zanzan University of Medical Science, Zanzan

City

Zanzan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanzan 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

Zanzan University of Medical Science

Full name of responsible person

Kambiz Eftekhari

Position

Assistant Professor

Other areas of specialty/work

Street address

Mousavi Hospital

City

Zanzan

Postal code

4513956183

Phone

+98 24 3313 0001

Fax

Email

dr_k_eftekhary@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanzan University of Medical Science

Full name of responsible person

Kambiz Eftekhari

Position

Assistant Professor

Other areas of specialty/work

Street address

Mousavi Hospital

City

Zanzan

Postal code

4513956183

Phone

+98 24 3313 0001

Fax

Email

dr_k_eftekhary@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor

Other areas of specialty/work**Street address**

Mousavin Hospital

City

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0001

Fax**Email**

dr_k_eftekhary@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