Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of effect of motilium as adjuvant therapy with polyethylene glycol in treatment of chronic functional constipation in children in comparison to placebo

Protocol summary

Summary

This study is a double blind clinical trial that perform in two groups of 50 children aged less than 12 year with chronic functional constipation. These two groups will be sex and age matched. For treatment of constipation, family education, diet, regular toilet training and disimpaction will be the same in both groups. One group will be treating with polyethylene glycol 0.6 mg/kg/day twice daily for six months and motilium 0.15 mg/kg/day three times per day for three months. Another group will be treating with the same dose of polyethylene glycol for six months and placebo for three months. The bottles are tagged by pharmacist as code 01 and 02. The patients refer to pharmacist and he prescribes polyethylene glycol and 01 or 02 syrup every other one. All patients will be following at one, three and six months after trial. In each visit Rome III criteria are evaluated and persistence of less than two criteria will considering as response to treatment. Finally two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204259101N2**
Registration date: **2012-06-13, 1391/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-13, 1391/03/24

Registrant information

Name

Seyed Mohsen Dehghani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of motilium as adjuvant therapy with polyethylene glycol in treatment of chronic functional constipation in children in comparison to placebo

Public title

Evaluation of effect of motilium in treatment of chronic functional constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having Rome III criteria for definition of functional constipation. Two or more of the following in a child with a developmental age of at least 4 years with insufficient criteria for diagnosis of inflammatory bowel

syndrome: Two or fewer defecations in the toilet per week; At least 1 episode of fecal incontinence per week; history of retentive posturing or excessive volitional stool retention; History of painful or hard bowel movements; Presence of a large fecal mass in the rectum; History of large diameter stools Criteria fulfilled at least once per week for at least 2 months before diagnosis, and one month of at least two of the following in infants up to 4 years of age: Two or fewer defecations per week; At least one episode/week of incontinence after the acquisition of toileting skills; History of excessive stool retention; History of painful or hard bowel movements ; Presence of a large fecal mass in the rectum; History of large diameter stools. The exclusion criteria: constipation due to any organic causes such as Hirschsprung disease, hypothyroidism, anal stenosis or use of medications that cause constipation.

Age
From **1 year** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **105**

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
Shiraz University of Medical Sciences

Street address
Zand Street

City
Shiraz

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
89-01-01-2580

Health conditions studied

1

Description of health condition studied
chronic constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
constipation

Timepoint
before intervention, one month and three months after intervention, and three months after the end of intervention

Method of measurement
Rome III criteria

Secondary outcomes

empty

Intervention groups

1

Description
Treatment with polyethylene glycol 0.6 gram/Kg/day two times a day for 6 months and motilium syrup 0.15 mg/Kg/dose three times a day for 3 months (1 mL=1 mg Syrup)

Category
Treatment - Drugs

2

Description
Treatment with polyethylene glycol 0.6 gram/Kg/day two times a day for 6 months and placebo syrup 0.15 mL/Kg/dose three times a day for 3 months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz University of Medical Sciences

Full name of responsible person

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Gholamreza Hatam
Street address
Nemazee Hospital
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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Full name of responsible person
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Person responsible for updating data

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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