# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

15 Jun 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)

**Phone**

+98 71 1626 1775

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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**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Seyed Mohsen Dehghani
**Position**
Associate Professor
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*