

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The Role of Synbiotic in the Treatment of Childhood Constipation

#### Protocol summary

##### Summary

Constipation is a common problem in children. There is some clinical evidence for the role of probiotics in the treatment of constipated children. This study is about the therapeutic effect of synbiotic (combination of probiotic and prebiotic) in treatment of childhood constipation. In a double-blind randomized placebo controlled study (RCTs) 102 children, aged 4-12 years, with functional constipation according to Rome III criteria were assessed for 4 weeks. They were randomized in 3 groups: Group A received 1.5 ml/kg/day oral liquid paraffin plus placebo, group B received 1 sachet of synbiotic per day plus placebo and group C received 1.5 ml/kg/day oral liquid paraffin plus 1 sachet of synbiotic per day. Frequency of bowel movements (BMs), stool consistency, number of fecal incontinence episodes, abdominal pain, painful defecation per week, success treatment, and side effects determined in each group before and after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138811193309N1**

Registration date: **2010-04-20, 1389/01/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-04-20, 1389/01/31

##### Registrant information

##### Name

Mozhgan Sabbaghian

##### Name of organization / entity

Department of Gastroenterology, Children's Medical Center Hospital, Tehran University of Medical Sc

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 1442 1904

##### Email address

sabbaghian@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2009-03-21, 1388/01/01

##### Expected recruitment end date

2010-03-01, 1388/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Role of Synbiotic in the Treatment of Childhood Constipation

##### Public title

The Role of Synbiotic in the Treatment of Childhood Constipation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age 4-12 years, diagnosis based on Rome III criteria as two months of at least 2 or more of the following: less than 2 defecation in the toilet per week, more than 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 that may obstruct the toilet. Exclusion criteria: presence of organic causes for constipation; including Hirschsprung's disease, spina bifida occulta, hypothyroidism, cystic fibrosis, neurologic abnormalities and intestinal pseudo-

obstruction

### Age

From **4 years** old to **12 years** old

### Gender

Both

### Phase

1

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### 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

Research Deputy of Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Science, 16 Azar St.

##### City

Tehran

##### Postal code

#### Approval date

2010-02-08, 1388/11/19

#### Ethics committee reference number

88/ S /130/1771

## Health conditions studied

### 1

#### Description of health condition studied

Other diseases of intestines

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

## Primary outcomes

### 1

#### Description

Frequency of bowel movements per week

#### Timepoint

4 weeks

#### Method of measurement

Questionnaire

### 2

#### Description

Stool consistency

#### Timepoint

4 Weeks

#### Method of measurement

Questionnaire

### 3

#### Description

Frequency of stool incontinence per week

#### Timepoint

4 Weeks

#### Method of measurement

questionnaire

### 4

#### Description

Abdominal pain

#### Timepoint

4 weeks

#### Method of measurement

questionnaire

### 5

#### Description

Painful defecation

#### Timepoint

4 weeks

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Success treatment

#### Timepoint

4 weeks

#### Method of measurement

Success treatment defined as  $\geq 3$  Bowel Movements per week,  $\leq 2$  incontinence per month and no abdominal pain

### 2

#### Description

Adverse effects

#### Timepoint

4 weeks

#### Method of measurement

Questionnaire

## Intervention groups

1

### Description

1.5 ml/kg/day oral liquid paraffin plus placebo (placebo sachet with the same shape and color to synbiotic)

### Category

Treatment - Drugs

2

### Description

1 sachet of synbiotic per day (Restore 1 billion CFU/1 sachet, Made by Protexin Co. in UK, synbiotic combination were probiotic strains containing L. casei, L. rhamnosus, S. thermophilus, B. breve, L. acidophilus, B. infantis and Fructooligosaccharide as prebiotic) and placebo (with the same shape and color to paraffin oil)

### Category

Treatment - Drugs

3

### Description

1.5 ml/kg/day oral liquid paraffin and 1 sachet of synbiotic per day (Restore 1 billion CFU/1 sachet, Made by Protexin Co. in UK, synbiotic combination were probiotic strains containing L. casei, L. rhamnosus, S. thermophilus, B. breve, L. acidophilus, B. infantis and Fructooligosaccharide as prebiotic)

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Children Medical Center Hospital

#### Full name of responsible person

Mozhgan Sabbaghian

#### Street address

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mozhgan Sabbaghian

#### Street address

Department of Gastroenterology, Children Medical Center Hospital, Tehran University of Medical Science

#### City

Tehran

#### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Manijh Khalili

#### Position

Fellowship of gastroentrlogy

#### Other areas of specialty/work

#### Street address

Department of Gastroenterology, Children's Medical Center Hospital, Tehran University of Medical Science

#### City

Tehran تهران

#### Postal code

#### Phone

+98 21 2213 0265

#### Fax

#### Email

dr\_khalili2000@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Ahmad Khodadad

#### Position

Associate Professor

#### Other areas of specialty/work

#### Street address

Department of Gastroenterology, Children's Medical Center Hospital, Tehran University of Medical Science

مرکز طبی کودکان

#### City

Tehran

#### Postal code

#### Phone

+98 21 6692 4545

#### Fax

**Email**

khodadadmd@yahoo.com

**Web page address****Fax****Email**

mozhgan\_sabbaghian@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mozhgan Sabbaghian

**Position**

Fellowship

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

Department of Gastroenterology, Children Medical  
Center Hospital, Tehran University of Medical Science

**City**

Tehran

**Postal code****Phone**

+98 26 1442 1904

**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*