

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The role of probiotics in treatment of chronic constipation in children

Protocol summary

Summary

To evaluate the efficacy of probiotics compared to paraffin for treatment of chronic constipation in pediatric population aged between 2-16 years, 60 children between 2-16 years who have chronic constipation will be randomly assigned. First group received 1.5 grams per kilogram of body weight of Paraffin and Pidrolax and second group received Pidrolax and probiotics. Symptoms evaluated by physician at baseline, 4th week and 8th week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409015330N7**

Registration date: **2014-11-27, 1393/09/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-27, 1393/09/06

Registrant information

Name

Mandana Rafeey

Name of organization / entity

Liver and gastrointestinal research center, Tabriz

University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1331 4135

Email address

rafeem@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

VICE-CHANCELLOR FOR RESEARCH OF TABRIZ
UNIVERSITY OF MEDICAL SCIENCES

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-09-20, 1393/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of probiotics in treatment of chronic constipation in children

Public title

Effect of probiotics in children constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: History of childhood constipation ; Ranged in age from 2 to 16 years

Exclusion criteria include: There is an organic cause for constipation; A drug that affects the bowel movements; Obstruction or stenosis of the gastrointestinal tract; Lack of consent to continue the study for any reason; The drug intolerant or intolerable side effects for the patient

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

blindness for control and interventional group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz university of medical sciences, Golgasht Av, Tabriz

City

Tabriz

Postal code

Approval date

2013-08-19, 1392/05/28

Ethics committee reference number

5/4/4668

Health conditions studied

1

Description of health condition studied

Chronic constipation in children

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Defecation frequency more than 3 times in a week and stool consistency

Timepoint

Baseline, week 4, week 8

Method of measurement

Clinical Evaluation

Secondary outcomes

1

Description

Faecal incontinence episodes less than one time in a week

Timepoint

Baseline, week 4, week 8

Method of measurement

Clinical Evaluation

Intervention groups

1

Description

Control group: receive 1.5 grams per kilogram of body weight Parrafin and Pidrolax

Category

Treatment - Drugs

2

Description

Interventional group: receive probiotics and Pidrolax

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz children Hospital

Full name of responsible person

Dr Mandana Rafeey

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

VICE-CHANCELLOR FOR RESEARCH OF TABRIZ UNIVERSITY OF MEDICAL SCIENCES

Full name of responsible person

Farzaneh Fakhimaliakbari

Street address

Children Hospital, Sheshgelan, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

VICE-CHANCELLOR FOR RESEARCH OF TABRIZ 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**

Tabriz university of medical sciences

Full name of responsible person

Dr Mandana Rafeey

Position

professor

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

Children Hospital, Shishgalan, Tabriz

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Resident

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Position

Proffesor of pediatric gastroentrology

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Children hospital, Shishgalan, Tabriz

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