

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Efficacy of probiotics in infantile colic

#### Protocol summary

##### Summary

To evaluate the efficacy of probiotics compared with routine treatment of infantile colic 60 infants between 0 to 3 months, will be randomly assigned. First group received routine treatment and second group received probiotics and routine treatment. Symptoms will be evaluated by physician at baseline, second week and 4th week. The daily number of crying episodes, sleep duration, crying duration and other clinical symptoms were assessed by a questionnaire. The questionnaire filled and reported by mother, was used to evaluate the response of treatment of infantile colic symptoms

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201409015330N8**  
Registration date: **2015-11-06, 1394/08/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-11-06, 1394/08/15

##### 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

rafieem@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

VICE-CHANCELLOR FOR RESEARCH OF TABRIZ  
UNIVERSITY OF MEDICAL SCIENCES

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of probiotics in infantile colic

##### Public title

Survey in efficacy of probiotics in infantile colic

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria :Babies with infantile colic aged 0 to 2 months  
Exclusion criteria: malnutrition; using antibiotics; cow's milk protein allergy

##### Age

From **1 month** old to **3 months** old

##### Gender

Both

##### Phase

2

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **60**

##### Randomization (investigator's opinion)

Randomized

##### Randomization description

##### Blinding (investigator's opinion)

Single blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Our study is simple sampling randomised with accidental numbers

## 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

2015-01-03, 1393/10/13

#### Ethics committee reference number

9431/4/5

## Health conditions studied

### 1

#### Description of health condition studied

Infantile colic

#### ICD-10 code

k93.8

#### ICD-10 code description

Disorders of other specified digestive organs in diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Daily time crying

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

### 2

#### Description

Sleep duration

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

### 3

#### Description

Feeding changes

#### Timepoint

Baseline,week2,week4

#### Method of measurement

mother report

### 4

#### Description

Defecation frequency

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

## Secondary outcomes

### 1

#### Description

Pediatric visits

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

### 2

#### Description

Emergency department accesses

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

### 3

#### Description

Loss of parents working days

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

### 4

#### Description

Use of multiple drugs

#### Timepoint

Baseline,week2,week4

#### Method of measurement

Mother report

## Intervention groups

**1**

**Description**

Interventional group received 1 sachet of supplement protexin daily and routine drugs

**Category**

Treatment - Drugs

**2**

**Description**

Control group receive routine drugs for colic.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tabriz children hospital

**Full name of responsible person**

Dr Mandana Rafeey

**Street address**

Children Hospital,Sheshgelan,Tabriz

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

VICE-CHANCELLOR FOR RESEARCH OF TABRIZ  
UNIVERCITY OF MEDICAL SCIENCES

**Full name of responsible person**

Dr Mohammad reza Rashidi

**Street address**

Tabriz univercity of medical science

**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  
UNIVERCITY 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,Sheshgelan,Tabriz

**City**

Tabriz

**Postal code**

5136735886

**Phone**

+98 41335262250

**Fax**

+98 41 3526 2280

**Email**

Rafeem@tbzmed.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz univercity of medical sciences

**Full name of responsible person**

Dr Mandana Rafeey

**Position**

Proffesor of pediatic gastroentrology

**Other areas of specialty/work**

**Street address**

Children hospital,Sheshgelan,Tabriz

**City**

Taabriz

**Postal code**

5136735886

**Phone**

+98 41 3526 2250

**Fax**

+98 41 3526 2280

**Email**

mrafeey@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz univercity of medical sciences

**Full name of responsible person**

Farnaz Golshaeian

**Position**

Resident

**Other areas of specialty/work**

**Street address**

Children Hospital,Sheshgelan,Tabriz

**City**

Tabriz

**Postal code**

5136735886

**Phone**

+98 41 3526 2250

**Fax**

+98 41 3526 2280

**Email**

f.golshaeian@gmail.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*