# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Investigation of probiotic efficacy compared with placebo in decreasing the crying time in infants involved with infantile colic

## Protocol summary

**Summary**

The objective of this study was to investigate the probiotic efficacy in treatment of the infantile colic compared with placebo. The 15-120 day old , breastfed Infants crying for 3 hours or more per day and 3 days or more per week entered to the study. The exclusion criteria were consumption of formula or antibiotics or finding another etiology for the infant crying. About 60 infants were randomly divided into two groups. The first group received the probiotic mixture "Protexin" one sachet daily for 30 days . The second group received the placebo one sachet daily for 30 days . We recorded the daily crying time before start of the drug and on the 7th and 30th days.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201205209808N1**
Registration date: **2013-04-20, 1392/01/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2013-04-20, 1392/01/31

**Registrant information**

**Name**

Aminreza Amini

**Name of organization / entity**

Mashhad University of Medical Sciencs, Faculty of Health Science

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 1501 9748

**Email address**

aminiar901@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor of Research, Mashhad University of Medical Sciences

**Expected recruitment start date**

2010-01-03, 1388/10/13

**Expected recruitment end date**

2012-08-22, 1391/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of probiotic efficacy compared with placebo in decreasing the crying time in infants involved with infantile colic

**Public title**

Investigation of the effects of Probiotics on Infantile Colic

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion Criteria: Infant ; birth weight between 2 and 4 Kg ; breast mother feeding ; no drug consumption ; diagnosis of the infantile colic (keep crying for 3 hours or more per day and 3 days or more per week) Exclusion Criteria: Infants with age less than 15 or more than 120 days ; birth weight less than 2 or more than 4 Kg ; formula consumption ; antibiotic consumption ; finding another cause for the infant crying

**Age**

To **1 year** old

**Gender**

Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Mshhad University of Medical Sciences
**Street address**
Daneshgah Street- Ghoreyshi Building
**City**
Mashhad
**Postal code**
91375-345
**Approval date**
2009-12-29, 1388/10/08
**Ethics committee reference number**
88023

## Health conditions studied

**1**

**Description of health condition studied**
Iinfantiel Colics
**ICD-10 code**
R10.4
**ICD-10 code description**
Other and unspecified abdominal painAbdominal tenderness NOS

## Primary outcomes

**1**

**Description**
duration and frequency of crying
**Timepoint**
7 and 30 days after intervention
**Method of measurement**
duration of crying is measured in minute, based on questionnaires

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
In the probiotic group : administration of the probiotic mixture named “protexin” orally in amount of one sachet per day for 30 days
**Category**
Treatment - Drugs

**2**

**Description**
In the placebo group : administration of the placebo orally in amount of one sachet per day for 30 days
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ghaem Hospital
**Full name of responsible person**
Dr. Hamidreza Kianifar
**Street address**
Ahmadabad Street/Qaem Hospital
**City**
Mashhad

**2**

**Recruitment center**
**Name of recruitment center**
Dr. Sheikh Hospital
**Full name of responsible person**
Hamid Ahanchian
**Street address**
Motahari Street/Dr Sheikh Hospital
**City**
Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr. Mohsen Tafaghody
**Street address**
Vakil Abad Blvd- Mahshad University of Medical

Sciences- School of Pharmacy, Department of Pharmaceutics

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Science

**Full name of responsible person**

Dr. Zeinab Noorbakhsh

**Position**

Pediatric Assistant

**Other areas of specialty/work**

**Street address**

No31,Aref the 3rd,Ahmadabad st

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1843 2115

**Fax**

**Email**

Noorbakhsh1362@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Hamidreza Kianifar

**Position**

Assistant Professor of Pediatric

**Other areas of specialty/work**

**Street address**

Ahmadabad st- Ghaem Hospital

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1840 0001

**Fax**

**Email**

KianifarHR@mums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Zeinab Noorbakhsh

**Position**

Resident of Pediatrics

**Other areas of specialty/work**

**Street address**

Ahmadabad Street/Qaem Hospital

**City**

Mashhad

**Postal code**

**Phone**

+98 84 00001

**Fax**

**Email**

Noorbakhsh1362@gmail.com

**Web page address**

www.mums.ac.ir/emamreza

## 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*