

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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 Sciences, 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**

infantiel 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**

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## Person responsible for scientific inquiries

**Contact**

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Hamidreza Kianifar

**Position**

Assistant Professor of Pediatric

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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**Position**

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**Other areas of specialty/work**

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## 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*