Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 recieved 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 duratin and other clinical symptoms were assessed by a questionnaire.The questionnare 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)

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+98 41 1331 4135

Email address
rafieem@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

VICE-CHANCELLOR FOR REASEARCH OF TABRIZ UNIVERCITY 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 commitee 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
Defication 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 recieve 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
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Person responsible for updating data

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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