Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of the effectiveness of preinatal administration Lactobacillus Reuteri on prevention of Infantile Colic

Protocol summary

Study aim

The aim of the study is determining the role of prenatal administration of Lactobacillus Reuteri on prevention of infantile colic.

Design

double-blinded, placebo-controlled, randomized clinical trial

Settings and conduct

After randomization and providing patients with the medications, mothers' ages, body mass index (BMI), and gestational ages will be calculated and documented. The infants' gender and feeding pattern distribution will also be documented in the first physical examination session. During a 5-month follow-up period, infants will repetitively be examined by the blinded pediatrics assistant (every two weeks by 60 days of age and every 30 days for the rest of the follow-up). Should any of the infants be diagnosed with infantile colic during the follow-up period, the assistant will document it and assess the signs of infantile colic and its severity.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women; with the age of 18-49 years old; at last 4 weeks of pregnancy who HIV infection, renal and hepatic diseases, diabetes mellitus, and anemia are rulled out for them and absence of a history of smoking 10 or more cigarettes/day; absence of a history of using other probiotics; absence of any sign of present infection or antibiotic usage in the recent 30 days; absence of twin pregnancy Exclusion criteria Hypersensitivity to any components of drug, those who are being treated with anti-allergen drugs; patients unwilling to continue pregnancy or preterm labor; patients who do not receive international drug properly.

Intervention groups

Intervention to investigate the efficacy of L..Reuteri at the last month of pregnancy on prevention of infant colic in two groups of case with probiotic and control with placebo

Main outcome variables

infantile colic; severity of infantile colic

General information

Reason for update

Acronym

L. Reuteri (Lactobacillus Reuteri)

IRCT registration information

IRCT registration number: **IRCT20131004014882N7**
Registration date: **2019-09-08, 1398/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-08, 1398/06/17**
Update count: **0**

Registration date

2019-09-08, 1398/06/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-29, 1398/06/07

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of preinatal administration Lactobacillus Reuteri on prevention of Infantile Colic

Public title

Effect of prenatal administration of Lactobacillus Reuteri on prevention of Infantile Colic

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The last 4 weeks of pregnancy The absence of a history of maternal immunocompromising conditions such as HIV The absence of maternal diabetes, hepatic and renal diseases, anemia (hemoglobin less than 10), bacterial or fungal infections, twins, maternal smoking history of 10 cigarettes per day, or administration of other probiotics Maternal age between 18 and 49 years old All pregnant mothers who have informed consent to participate in the study.

Exclusion criteria:

Mother hypersensitivity to any component of drug Mothers who are not willing to continue pregnancy or who have had an early pregnancy due to complications of pregnancy Preterm labor Mothers who do not receive the drug properly

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **174**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use Random Allocation Software© Version 1.0, May 2004 in order to randomly arrange the patients into the two groups (L. Reuteri and placebo), using blocking and stratification methods. The physician who examines the infant (a pediatrics assistant) and the mothers will be blinded from the patient study groups. For randomization, patients will be handed a closed envelope and asked to deliver it to a gynecology and obstetrics assistant who then provides them the package containing the placebo (containing 9% glucose solution) or the probiotic drug (containing 100 million live L. Reuteri from Gostaresh Milad Pharmed® Prokid™ drop) dependent on the number existing in the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The mothers and the pediatric assistant who will repeatedly examine the infants on account of infantile colic, are blinded from the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features

Our goal is to give the pregnant mother the medicine at the end of pregnancy and its effect on the symptoms of colic in her infant after birth.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St.

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Province

Isfehan

Postal code

8174673461

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.MUI.MED.REC.1397.248

Health conditions studied

1

Description of health condition studied

Infantile colic is an “irritable/uncontrollable/compulsive/inconsolable crying” for more than 3 hours a day, at least for three days a week, and for a week or longer in an infant without any distinct cause or failure to thrive. The onset and impoverishment of the symptoms must occur under 5 months of age in order for the condition to be definite as infantile colic.

ICD-10 code

K59.9

ICD-10 code description

Functional intestinal disorder, unspecified

Primary outcomes

1

Description

The severity of colic

Timepoint

From birth to 5 months

Method of measurement

For the assessment colic severity, we used a validated Iranian questionnaire previously suggested by Famoori et al.

2

Description

infantile colic and severity

Timepoint

From birth to 5 months

Method of measurement

Defined by Wessel et al. and modified by ROME IV criteria as "irritable/uncontrollable/compulsive/inconsolable crying" for more than 3 hours a day, at least for three days a week, and for a week or longer in an infant without any distinct cause or failure to thrive. The onset and impoverishment of the symptoms must occur under 5 months of age in order for the condition to be definite as infantile colic.

Secondary outcomes

1

Description

prevention or reduction of severity of infantile colic

Timepoint

Birth to 5 months

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Mothers who receive probiotics:87 pregnant mother at the last 4 weeks of pregnancy enter to the study. The probiotic drug (containing 100 million live L. Reuteri from Gostaresh Milad Pharmed® Prokid™ drop). All patients were informed how and to use the medication (5 drops of the drug daily) up to end of pregnancy.

Category

Treatment - Drugs

2

Description

Control group: placebo consumption: Control group treated with placebo drops (including sugar and carbohydrates), exactly the same as the original drug developed by Gostaresh Milad Poya Co., with 5 drops until delivery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti Hospital of Isfahan medical science

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Fateme Famoori

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associateProfessor

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available