

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of probiotic supplementation on aflatoxin M1 levels in breast milk

Protocol summary

Study aim

Considering the importance of aflatoxin M1 toxin and its role in human health as well as the effects of its transfer from breast milk to infant, the aim of this study was to investigate the effect of probiotic supplementation on the amount of aflatoxin M1 toxin in breast milk.

Design

This study will be performed by phase 2 double-blind clinical trial. Forty breastfeeding mothers with full-term and healthy 2 to 4-month-old infants will be randomly selected and then randomly divided (using a random number table) into two groups of 20 (probiotic supplement and placebo). At the beginning of the study, the amount of aflatoxin in breast milk will be measured. Then, for 1 month, they will take 2 probiotic supplements or placebo daily (after lunch and dinner).

Settings and conduct

This study will be performed by a double-blind clinical trial. Forty breastfeeding mothers with full-term and healthy 2-4-month-old infants referred to Shahid Shamlu Abadan Pediatric Clinic will be randomly selected and divided into two groups of 20 (probiotic supplement and placebo). At the beginning, the milk sample will be prepared by the mother herself using a manual milking machine in a sterile plastic container of 10-15 ml. The collected milk samples will be immediately transferred to the laboratory in the cold chain and in the freezer at -20 ° C. will be maintained until analysis. The ELISA method is used to measure aflatoxin M1. Then they will take 2 probiotic supplements or a placebo (daily after lunch and dinner) for 1 month.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Breastfeeding mothers with babies 2 to 4 months No chronic diseases Exclusion criteria: Mothers with chronic diseases

Intervention groups

two groups (probiotic supplement and placebo). Then they will take 2 probiotic supplements or a placebo daily for 1 month.

Main outcome variables

Decreased aflatoxin M1 in breast milk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200326046868N2**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **prospective**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

Reza Malihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5326 7800

Email address

r.malihi@abadanums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-25, 1399/07/04

Expected recruitment end date

2020-09-30, 1399/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotic supplementation on aflatoxin M1 levels in breast milk

Public title

The effect of probiotic supplementation on breast milk aflatoxin M1

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Breastfeeding mothers with babies 2 to 4 months NO chronic diseases

Exclusion criteria:

non breastfeeding mother without babies 2 to 4 months mothers with chronic disease

Age

From **20 years** old to **39 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this double blind study, Researchers and mothers have no information about the type of drug or placebo. Allocate mothers to two intervention and control groups so that the list of subjects studied will be randomly generated by a computer. The intervention and control group will be placed inside the numbered envelopes and will be sealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the participants in the trial are not aware of which probiotics or drugs they are taking. Probiotics and placebo are given to the case and control group by a third person who is a clinical attentive

Placebo

Used

Assignment

Other

Other design features

In this study, we have two groups of control and case, which are given probiotics to the case group and placebo to the control group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Abadan School of Medical Sciences

Street address

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

City

Abadan

Province

Khouzestan

Postal code

631911154 061

Approval date

2020-02-15, 1398/11/26

Ethics committee reference number

IR.ABADANUMS.REC.1398.078

Health conditions studied**1****Description of health condition studied**

Aflatoxin contamination

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of aflatoxin M1 in breast milk

Timepoint

Measuring the amount of aflatoxin in breast milk At the beginning of the study and then for 1 month according to the divided group, they will take 2 probiotic supplements or placebo (daily after lunch and dinner). After the intervention, the amount of aflatoxin in breast milk will be measured again.

Method of measurement

At the beginning of the study, the milk sample will be prepared by the mother herself using a manual milking machine in a sterile plastic container of 10-15 ml. The collected milk samples will be immediately transferred to the laboratory in the cold chain and in the freezer at -20 ° C. C will be maintained until analysis. ELISA is used to measure aflatoxin M1.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will take 2 probiotic supplements daily (after lunch and dinner) for 1 month. It is worth mentioning that in this study, several species of probiotic supplements (FamiLact co, Tehran, Iran) will be used, which include 7 stable and frozen strains: Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium, Streptococcus thermophilus This supplement is an oral capsule with Kant CFU 109.

Category

Treatment - Drugs

2

Description

Control group: They will take 2 probiotic supplements daily (after lunch and dinner) for 1 month. The company will provide researchers with similar bacteria-free materials as a placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Shamli Abadan Children's Clinic

Full name of responsible person

Armin Khaleghjo

Street address

Ahmadabad, Shahid Shamli Clinic, Shahid Beheshti Hospital, Abadan, Iran

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drykhaleghjoo@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

Sara Mobarak

Street address

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan, Iran

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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

Abadan 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

Abadan University of Medical Sciences

Full name of responsible person

Armin Khaleghjo

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Abadan University of Medical Sciences

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Person responsible for updating data**Contact****Name of organization / entity**

Abadan University of Medical Sciences

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information can be shared

When the data will become available and for how long

From 2021 onwards

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific-research purposes

From where data/document is obtainable

Email the respondent

What processes are involved for a request to access data/document

via Email

Comments