

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of probiotic consumption versus placebo in lactating mothers with low birth weight or very low birth weight infants on weight gain, serum bilirubin level and the incidence of necrotizing enterocolitis: a triple-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of probiotic consumption versus placebo in lactating mothers with low birth weight or very low birth weight infants on weight gain, serum bilirubin level and the incidence of necrotizing enterocolitis

Design

This is a triple-blind randomized clinical trial with control group, phase III, in which eligible 60 eligible lactating mothers with low birth weight or very low birth weight infants will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 60 eligible lactating mothers with low birth weight or very low birth weight infants. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be triple-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 15 to 45 years Mothers with low birth weight or very low birth weight infants Exclusion criteria: A baby who is not able to feed with breast milk

Intervention groups

Intervention group: Oral Kidilact sachet (probiotic + prebiotic) 1 gr once daily for 28 days Control group: Oral placebo (starch) sachet once daily for 28 days

Main outcome variables

Primary outcome: The mean weight of the baby, the mean serum bilirubin Secondary outcome: occurrence of necrotizing enterocolitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N466**

Registration date: **2023-03-30, 1402/01/10**

Registration timing: **prospective**

Last update: **2023-03-30, 1402/01/10**

Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic consumption versus placebo in lactating mothers with low birth weight or very low birth weight infants on weight gain, serum bilirubin level and the incidence of necrotizing enterocolitis: a triple-blind randomized clinical trial

Public title

Effect of probiotic consumption versus placebo in lactating mothers with low birth weight or very low birth weight infants on weight gain, serum bilirubin level and the incidence of necrotizing enterocolitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 15 to 45 years Mothers with low birth weight or very low birth weight infants

Exclusion criteria:

A baby who is not able to feed with breast milk

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drugs will be given in coded envelopes. Therefore, patients will be unaware of the type of intervention. The person who gives the medicine and the one who examines the patients will be different thus the physician who will examine the patients will not be aware of the intervention. The groups under study are entered in the software in coded form and analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

IR.UMSHA.REC.1401.1003

Health conditions studied

1

Description of health condition studied

Low birth weight

ICD-10 code

P07.0

ICD-10 code description

Extremely low birth weight newborn

Primary outcomes

1

Description

The mean weight of the newborns

Timepoint

Before the intervention and on the 14th and 28th days after the intervention

Method of measurement

Using weights

2

Description

The mean serum bilirubin level of newborns

Timepoint

Before the intervention and on the 14th and 28th days after the intervention

Method of measurement

Using a laboratory test

Secondary outcomes

1

Description

Occurrence of necrotizing enterocolitis

Timepoint

28 days after the intervention

Method of measurement

By taking history and clinical examination

Intervention groups

1

Description

Intervention group: Oral Kidilact sachet (probiotic + prebiotic) 1 gr once daily for 28 days

Category

Treatment - Drugs

2

Description

Control group: Oral placebo (starch) sachet once daily for 28 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Fatemeh Sharaflari

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

sarasharaflari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Sharaflari

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

sarasharaflari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Maryam Ahmadi

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

ahmadi_1011@yahoo.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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