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 Fatemieh 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
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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
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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
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Sponsors / Funding sources

1

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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
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
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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