Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2026

The effect of probiotic administration to mothers with low birth weight neonates on some of the neonatal and maternal outcomes

Protocol summary

Study aim

Determining the effect of probiotic administration to mothers with low birth weight neonates on some of the neonatal and maternal outcomes

Design

Randomized, superiority, placebo-controlled, double-blind trial with two parallel arms: 122 participants will be equally randomized into the groups using stratified block randomization referring to a computerized program

Settings and conduct

In Al-Zahra teaching hospitals in Tabriz, eligible infants and their mothers will be studied after receiving informed written consent from the mothers and if possible from fathers. The participants, those administering the interventions, care providers, and those collecting and analyzing data will be blinded.

Participants/Inclusion and exclusion criteria

Participants will be mothers with low birth weight (1000 to 2000 g) infants. The mothers should have given birth in the past 48 h, have the desire and ability to breastfeed, and be able to attend the hospital at least once a week. The infants should be hospitalized for at least 7 days after starting the intervention. Exclusion criteria include triplets or more, infant's bad condition, contraindications to breastfeeding, the existence of obvious anomalies in the neonate, regular use of probiotics (in any form) by the mother, history of probiotic allergy or existence of immunity disorders in the mother, and unwillingness to participate in the study.

Intervention groups

Mothers will receive probiotic supplement in the intervention group and placebo in the control group, one capsule a day for 6 weeks.

Main outcome variables

Level of total serum bilirubin in the neonate at the fourth and seventh days of intervention, and postpartum depression (40-45 days of the intervention)

General information

Reason for update

Due to the challenge of finding mothers with infants weighting between 1000 and 1500 g and the extended sampling period, the Research Council approved an expansion of the infant weight range to 1000 to 2000 g. Additionally, it was determined that stratified allocation based on infant birth weight (1000 to 1500 g and 1501 to 2000 g) would be implemented, along with consideration of the previous stratified factor of number of fetuses (singleton/twin).

Acronym

IRCT registration information

IRCT registration number: **IRCT20100414003706N42**
Registration date: **2022-11-22, 1401/09/01**
Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**
Update count: **1**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name
Sakineh Mohammad-Alizadeh-Charandabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

2022-12-30, 1401/10/09

Actual recruitment end date

2023-10-31, 1402/08/09

Trial completion date

2023-11-15, 1402/08/24

Scientific title

The effect of probiotic administration to mothers with low birth weight neonates on some of the neonatal and maternal outcomes

Public title

The effect of probiotic administration to mothers with low birth weight neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Neonatal birth weight of 1000 to 2000 g Delivery in the past 48 h Hospitalization of the infant for at least 7 days after the start of the intervention Possibility of the mother to attend the hospital where the baby is admitted, at least once a week Desire and ability to breastfeed her baby

Exclusion criteria:

Triplets or more Bad condition of the infant diagnosed by a neonatologist contraindications for feeding the infant with breast milk Existence of obvious anomalies in the neonate Regular use of probiotics (in any form) by the mother History of sensitivity to probiotics in the mother Immunodeficiency in the mother

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **122**

Actual sample size reached: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be individually randomized into intervention or control groups using stratified (single/twin pregnancy and infant birth weight (1000-15000/1501-2000)) block randomization with a block size of four and a ratio of 1:1. Allocation sequence will be generated using a computerized program. Identical sequentially numbered bottles containing probiotic or placebo capsules will be used to conceal the sequence and enable blinding.

Blinding (investigator's opinion)

Double blinded

Blinding description

Probiotic supplements and placebo will be prepared in identical shapes, colors, smells, and packages. The sequence generation and preparation of the packs will be done by a person not involved in participant recruitment or data collection. Identical sequentially numbered bottles containing probiotic or placebo capsules will be used to conceal the allocation sequence and enable blinding. The persons administering the interventions, health care providers, outcome assessors, and statistical analysts will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-11-14, 1401/08/23

Ethics committee reference number

IR.TBZMED.REC.1401.735

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia (Jaundice)

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

2

Description of health condition studied

Postpartum depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

3

Description of health condition studied
Mastitis
ICD-10 code
O91.22
ICD-10 code description
Nonpurulent mastitis associated with the puerperium

Primary outcomes

1

Description
Total serum bilirubin level in newborn
Timepoint
The fourth and seventh days of intervention
Method of measurement
laboratory assessment

2

Description
Postpartum depression
Timepoint
Baseline, 40-45 days after birth
Method of measurement
The Edinburgh Postpartum Depression Scale

Secondary outcomes

1

Description
Infant weight gain during 40-45 days
Timepoint
At baseline, 7th day of the intervention, discharge day, and 40 to 45 days after birth
Method of measurement
Using a digital scale

2

Description
Total duration of phototherapy (hours)
Timepoint
During neonatal period
Method of measurement
Daily assessment of infant medical record

3

Description
Duration of infant hospitalization
Timepoint
Until discharge from the hospital (if discharged earlier than 40 - 45 days, assessment after 40 -45 days for re-admission to hospital)
Method of measurement
Assessment of infant medical record and contact with the mother after 40 - 45 days in case of early discharge

4

Description
The composite variable of occurrence of serious neonatal problems (including bronchopulmonary dysplasia, sepsis, necrotizing enterocolitis, or retinopathy of prematurity)
Timepoint
40- 45 days of infancy
Method of measurement
Diagnosed by a neonatologist and an ophthalmologist based on clinical and para-clinical assessments (Retinopathy of prematurity will be assessed by an ophthalmologist after 28 days of infancy) which is recorded in the medical records.

5

Description
Occurrence of mastitis in the mother
Timepoint
During 40 -45 days of childbirth
Method of measurement
Using the Mastitis scale

6

Description
Postpartum anxiety
Timepoint
40-45 days after birth
Method of measurement
Specific Postpartum Anxiety Scale

Intervention groups

1

Description
Intervention group: capsules of the probiotic supplement containing CFU/g 3×109 Lacticaseibacillus paracasei subsp. Paracasei and Bifidobacterium lactis (animals) will be given once a day for 6 weeks to the mothers.
Category
Prevention

2

Description
Control group: placebo capsules containing starch powder will be given once a day for 6 weeks to the mothers.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Al-Zahra hospital

Full name of responsible person
Dr Maryam Vaezie

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Bage-Shomal Intersection, South Artesh Ave., Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Maryam Alikamali

Position
PhD student in midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Professor

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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

The requested data will be provided to researchers for statistical analysis (meta-analysis) of the submitted proposal.

When the data will become available and for how long

starting immediately after the publication of the study results

To whom data/document is available

Data will be available to researchers working at academic organizations, as well as to the chief editor (and reviewers) of the journal of the submitted manuscript/s if requested.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of a proposal to perform a meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to the journal of submitted manuscript/s for checking the accuracy of the data

From where data/document is obtainable

Refer to the email address (alizades@tbzmed.ac.ir; mhammadalizadehs@gmail.com)

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

The requests will be sent by email and data will be available within two weeks.

Comments