

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 3×10^9 Lactocaseibacillus 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

Dr. Parviz Shahabi

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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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Nursing & Midwifery Faculty, South Shariati Ave.,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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