Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of probiotics on indirect bilirubin levels in neonates with neonatal jaundice in neonates hospitalized to Ayatollah Mousavi Hospital in Zanjan

Protocol summary

Study aim
Investigating the effect of probiotics on the amount of indirect bilirubin in hospitalized babies with jaundice

Design
A clinical trial with a control group with a parallel group that was randomized phase 3 on 120 patients.

Settings and conduct
Which is a clinical trial, 122 infants referred to Mousavi Hospital for the treatment of jaundice in infants who are going to be hospitalized will be selected and the conditions of the work will be explained and after obtaining the informed consent of the sample and after completing the criteria Entering the study to remove confounders, the samples will be randomly assigned to one of the two control and control groups, the control group will be treated with phototherapy, and the control group will be treated with Prokid in the form of 5 Daily drops will be added to other standard treatments.During hospitalization, the amount of bilirubin on the day of hospitalization and the first days of hospitalization and the second days and the rest of the days, the duration of the need for phototherapy, which will be expressed in hours or days, and the duration of hospitalization will be measured until at the end according to Necessary conclusions should be made to the measured variables.

Participants/Inclusion and exclusion criteria
1- Infants suffering from neonatal jaundice who have referred to Mousavi Zanjan Hospital and are indicated for hospitalization. 2- Babies for whom no fetal anomalies were mentioned before birth. 3- Babies whose jaundice is not pathological.

Intervention groups
In this study, the effectiveness of probiotics in reducing the level of indirect bilirubin will be investigated, which will be used for infants with non-pathological jaundice, and common treatments such as phototherapy and serum therapy will be used in the control group.

Main outcome variables
Number of days in hospital Hospital cost Serum bilirubin level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180311039048N1**
Registration date: **2023-12-23, 1402/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**
Update count: **0**

Registration date
2023-12-23, 1402/10/02

Registrant information

Name
Farzaneh Moezi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 24 3344 0087

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moezi@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotics on indirect bilirubin levels in neonates with neonatal jaundice in neonates hospitalized to Ayatollah Mousavi Hospital in Zanjan

Public title
The effect of probiotics on indirect bilirubin levels
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- Infants suffering from neonatal jaundice who have referred to Mousavi Zanjan Hospital and are indicated for hospitalization. 2- Babies for whom no fetal anomalies were mentioned before birth. 3- Babies whose jaundice is not pathological.
Exclusion criteria:
1- Babies whose jaundice started on the first day 2- Babies whose jaundice is related to biliary atresia 3- The baby's family is not satisfied.
Age
From **2 days** old to **2 months** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be simple. In order to have equal and independent conditions for all samples and eliminate any type of bias, a simple random method will be used to select samples in the intervention and control groups, which means that some people will be offered the use of probiotics completely by chance. The baby will be first explained to the parents about hospitalization, then a dice will be thrown, and if the dice number is even, he will enter the treatment group with probiotics, and if the number is odd, he will be treated with common treatments. Random allocation is done using Excel software. For this, in the first column, we enter 61 numbers 1 and 61 numbers 2 (representing the probiotic group and common treatments, respectively). Then, in the second column, we generate 122 random numbers using the RAND() function. We sort the data based on column values containing random numbers (ascending or descending). With this sorting, the order of placement of numbers 1 and 2 will also change and be placed randomly. Based on the order of appearance of numbers 1 and 2, the samples are assigned to two groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan university of Medical Sciences
Street address
Gavazang Street, Zanjan University of Medical Sciences
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2023-03-12, 1401/12/21
Ethics committee reference number
IR.ZUMS.REC.1401.371

Health conditions studied

1

Description of health condition studied
Jaundice in babies
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
The amount of indirect bilirubin that led to hospitalization
Timepoint
The first day of hospitalization, the second day of hospitalization, the third day of hospitalization
Method of measurement
By laboratory kits through blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the treatment of newborns, 5 drops of Procid brand probiotic will be used daily, and the medicine will be prescribed for 3 days.
Category
Treatment - Drugs

2

Description
Control group: This group of babies will receive routine treatments, including phototherapy and serum therapy, and Peroxide drops will not be used for these babies.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mosavi Hospital
Full name of responsible person
Azam karimi Asl
Street address
Gavazangi ;Mosavi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Samad Nadry
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zanjan university
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
Zanjan University of Medical Sciences
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Azam karimi Asl
Position
Associate Professor
Latest degree
Medical doctor
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Person responsible for updating data

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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 data will be accessible after de-identifying individuals
When the data will become available and for how long
Beginning of the access period from 2025
To whom data/document is available
Researchers
Under which criteria data/document could be used
It will be accessible by mentioning the source
From where data/document is obtainable
It will be available via email after correspondence
What processes are involved for a request to access data/document
After the correspondence, it should be available within a week
Comments