

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 Zanzan

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 Zanzan 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

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 0087

Email address

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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5618345139

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+98 914 323 6034

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karimi.aazam@yahoo.com

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

Full name of responsible person

Azam karimi Asl

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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

Zanjan University of Medical Sciences

Full name of responsible person

Farzaneh Moezi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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