

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effectiveness of probiotics against bilirubin increase in neonates below 2500 gram.

Protocol summary

Study aim

The effect of probiotics in preventing the increase of bilirubin in neonates weighting less than 2500 grams

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 2 and 3 per 100 patients. Excel software rand function was used for randomization.

Settings and conduct

In neonates admitted to the intensive care unit with inclusion criteria in the study. The intervention group received 5 drops of pedilact daily for 3 days from the first day and the probiotic control group was not given. Bilirubin levels are measured daily through the skin every 24 hours for 7 days

Participants/Inclusion and exclusion criteria

Inclusion criteria: Do not have heart failure and respiratory failure; Exclusion criteria: Critical neonates

Intervention groups

The intervention group will receive 5 drops of pedilact daily for 3 days from the first day and the probiotic control group will not be given.

Main outcome variables

Level of bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081021001378N13**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-29, 1400/10/08**

Update count: **0**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

Ahmadshah Farhat

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 1121

Email address

farhata@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-06, 1399/10/17

Expected recruitment end date

2022-01-07, 1400/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of probiotics against bilirubin increase in neonates below 2500 gram.

Public title

Effects of probiotics in bilirubin increase

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonate weighting less than 2,500 grams are not in critical condition Do not have krenictrose Do not have ventilation Do not have heart failure Do not have asphyxia and no history of Rh incompatibility Do not

have icterus

Exclusion criteria:

Critical neonates Phototherapy

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of infants will be done using block methods. A random sequence will be generated using four blocks of sealed envelope.com. The envelopes will be printed by the researcher after randomization and will be placed inside the envelopes and the envelope lids will be closed. Envelopes are numbered in random order. Then, we first explain the purpose of the study to the person and he / she will sign the informed consent and receive the intervention based on the envelope number and the order specified in it.

Blinding (investigator's opinion)

Single blinded

Blinding description

Considering that the babies do not have the necessary knowledge in this regard and the mothers have not been informed about this study, the study is therefore one-way blind and only the researcher who is performing the study knows.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreshi Bul, Daneshgah St, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2019-06-12, 1398/03/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.576

Health conditions studied

1

Description of health condition studied

hyperbilirubinemia

ICD-10 code

P59.0

ICD-10 code description

Neonatal jaundice associated with preterm delivery

Primary outcomes

1

Description

bilirubin

Timepoint

Daily for 7 days

Method of measurement

Through the surface of the skin

2

Description

Hospitalization period

Timepoint

Daily

Method of measurement

Number of days

Secondary outcomes

1

Description

Weight gain

Timepoint

Daily

Method of measurement

Balance

Intervention groups

1

Description

Intervention group: 5 drop pedilact zist takhmir probiotic .co. Iran daily for 3 days 5 ml/g from first day. And bilirubin level is measured every 24 hours for 7 days.

Category

Treatment - Drugs

2

Description

Control group: No pedilactzisttakhmir probiotic
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Nazli Parizadeh

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Ibn Sina Ave, Imam Reza Hospital, Mashhad,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Nazli Parizadeh

Position

Resident of Pediatrics

Latest degree

Specialist

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Title and more details about the data/document

All data can be shared after patients are made unidentifed

When the data will become available and for how long

data can be accessible 6 months after results are published

To whom data/document is available

Data can be accessible through an email to the corresponding author

Under which criteria data/document could be used

data will be available for researchers in universities and other scientific institution

From where data/document is obtainable

After sending a request email to the corresponding author , data will be sent in 1 month.

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

Carrying out analysis on data is permitted

Comments