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 sealedenvelope.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

Street address

Ibn Sina Ave, Imam Reza Hospital, Mashhad,Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3852 1121

Email

parizadehnazli@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreshi Bul, Daneshgah St, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3852 1121

Email

Parizadehnazli@gmail.com

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

Street address

Ibn Sina Ave, Imam Reza Hospital, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98-051-385211121

Email

parizadehnazli@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nazli Parizadeh

Position

Resident pediatirics

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Ibn Sina Ave, Imam Reza Hospital, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3852 1121

Email

parizadehnazli@gmail.com

Person responsible for updating data

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
Street address
Ibn Sina Ave, Imam Reza Hospital, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
91379133169
Phone
+98 51 3852 1121
Email
Parizadehnazli@gmail.com

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 unidentified
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