Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effectiveness of probiotics in the treatment of jaundice in term and near_term newborns

Protocol summary

Study aim
Investigating the effectiveness of probiotics in the treatment of jaundice in newborns
Design
Randomized clinical trial without blinded strain on 100 newborns with jaundice under treatment, who are divided into two intervention and control groups, and they differ only in terms of receiving probiotic drops, and to control confounding variables, logistic regression modeling methods were used. is used
Settings and conduct
Jaundiced newborns admitted to Mufaid Children's Hospital
Participants/Inclusion and exclusion criteria
Exclusion criteria include; Birth weight less than two kilos, birth age less than 35 weeks, physiological jaundice and bilirubin less than 15.Bilirubin is above 25 and requires blood exchange and the presence of co-morbidities in the newborn, as well as the parents' lack of consent
Intervention groups
Accelerating the effect of probiotic drops in the treatment of neonatal jaundice
Main outcome variables
The result of the study is the acceleration of the recovery of neonatal jaundice and no harm has been observed in the treatment with probiotic drops

General information

Reason for update
Acronym
EPN
IRCT registration information
IRCT registration number: **IRCT20231020059774N1**
Registration date: **2023-12-05, 1402/09/14**
Registration timing: **registered_while_recruiting**
Last update: **2023-12-05, 1402/09/14**
Update count: **0**
Registration date
2023-12-05, 1402/09/14

Registrant information
Name
Samereh Ghorbani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 912 495 6577
Email address
samikh1985@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2025-03-20, 1403/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of probiotics in the treatment of jaundice in term and near_term newborns

Public title
Investigating the effectiveness of probiotics in the newborns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

A newborn with a birth weight of more than 2 kg Childbirth age greater than 37 weeks Non-physiological jaundice and bilirubin more than 15 A newborn with bilirubin less than 25 A newborn doesnot need blood transfusion A newborn without abnormalities and comorbidities Parental consent

Exclusion criteria:

A newborn less than 2 days old Childbirth age less than 35 weeks Pathological jaundice A newborn with bilirubin above 20 A newborn with malformations and other co-morbidities A newborn needs a blood transfusion

Age

From **2 days** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the fact that with the simple randomization method, there was a possibility that the balance between the groups would not be established, the method of examining the random allocation plan will be block randomization (Permuted). (block randomization in such a way that 100 people (determined according to the sample size) Divide into 25 blocks by using blocks of 4 and then as concealment will be assigned to study groups. In this study, the main researchers and the patient's parents did not know about the randomization method and random block allocation by The epidemiologist will do the planning

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 Shahid beheshti University of Medical Sciences

Street address

Shariati St., above Hosseinieh Irshad, Mofid Children's Hospital

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2023-10-01, 1402/07/09

Ethics committee reference number

IR.SBMU.MSP.REC.1402.372

Health conditions studied

1

Description of health condition studied

Jaundice in infants and acceleration of treatment

ICD-10 code

P59

ICD-10 code description

Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description

Rapid decrease in bilirubinl

Timepoint

The beginning of hospitalization and the course of treatment and the time of discharge

Method of measurement

Bilirubin level in blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 newborns with jaundice will be randomly given 5 drops of (Reuteflor) probiotic daily and its effect on reducing the duration of hospitalization of infants compared to the control group will be investigated.

Category

Treatment - Drugs

2

Description

Control group: Randomly, 50 hospitalized newborns with jaundice in the control group will not be given probiotics and will only go through the course of treatment for jaundice in the hospital.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid hospital

Full name of responsible person
Samereh Ghorbani

Street address
Shariati Street, above Hosseinieh Irshad, Mofid Children's Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Reza Saidi

Street address
Shariati Street. Mofid Children's Hospital

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Samereh Ghorbani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
No decision has been made to share the data
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions and people who are also engaged in industry
Under which criteria data/document could be used
It does not need to be analyzed further
From where data/document is obtainable
وب سایت
What processes are involved for a request to access data/document
Access period 6 months after publication
Comments