

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 Hosseinih Irshad, Mofid Children's Hospital

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Postal code

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Email

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Web page address

<https://mch.sbm.ac.ir>

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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Web page address

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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

Street address

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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