

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effect of probiotics in the treatment of jaundice

Protocol summary

Study aim

Determining the effect of probiotics in the treatment of jaundice in neonates admitted

Design

The sample size is 90 people, which includes two groups of 45 people, which will be the intervention and control group (receiving phototherapy). Patients will be blocked by randomization and will be divided into two groups. Initially, the volume of blocks will be considered 6 and all text combinations from AAABBB will be listed and an exclusive code will be considered for each. Next, according to the sample size (90 people), 15 blocks will be selected and listed by simple randomization method. All processes will be performed under the supervision of an epidemiologist.

Settings and conduct

Study participants are blinded. Urmia University of Medical Sciences, Urmia Shahid Motahari Hospital For both INTENSIVE phototherapy groups, the double 12-lamp device manufactured by Tucson will be used from the beginning of hospitalization. For the study group, in addition, 5 drops of reuteflor will be given orally in the morning and until the serum bilirubin level is cleared every hour. It will be measured at 0, 24, 48 and 72 hours after hospitalization and the number of hospitalization days and hospitalization hours will be recorded in two groups. All measurements will be done in one center by an experienced laboratory technician with the same kits.

Participants/Inclusion and exclusion criteria

Neonates with jaundice and hospitalized

Intervention groups

The sample size is 90 people, which includes two groups of 45 people, which will be the intervention and control group (receiving phototherapy).

Main outcome variables

Serum bilirubin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220425054656N1**

Registration date: **2022-11-04, 1401/08/13**

Registration timing: **retrospective**

Last update: **2022-11-04, 1401/08/13**

Update count: **0**

Registration date

2022-11-04, 1401/08/13

Registrant information

Name

Nasim Khalilidizaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3328 4717

Email address

nasimkhalilidizaji@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotics in the treatment of jaundice

Public title

Evaluation of the effect of probiotics in the treatment of

jaundice

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Semester infants with jaundice
Exclusion criteria:
Hospitalized infants with a diagnosis of jaundice who have sepsis 2 admitted with a diagnosis of jaundice who have respiratory distress Increased jaundice with the necessary amounts for blood transfusion Jaundice due to blood group incompatibility and RH Direct hyperbilirubinemia Infants with severe congenital anomalies

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were blocked by simple randomization method and divided into two groups. At first, the size of the blocks will be considered 6 and all possible combinations from AAABBB will be listed and an exclusive code will be considered for each one. Further, according to the sample size (90 people), 15 blocks will be selected by simple randomization method. (lottery) was selected and listed. All processes were done under the supervision of an epidemiologist and using random allocation software. Random allocation software version 1.0.0, which was created by M. Saghaei, department of anesthesia, Isfahan university of medical sciences, Isfahan, Iran, and is one of the most widely used software for randomization, which according to the sample size and the number of groups blocks and the size of the blocks completely randomly presents the number and combinations of the necessary blocks, in the order of the blocks and combinations given by the software and assigning exclusive codes for each, which these combinations and codes are hidden and only in It is the authority of the epidemiology consultant and the order of entry of people will be based on them, only if any complications or problems are observed in the continuation of the study, these codes will be referred to in order to identify the people.

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 Urmia University of Medical Sciences

Street address

Urmia, Resalat Boulevard, Emergency Alley

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.UMSU.REC.1401.012

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

R17

ICD-10 code description

Hyperbilirubinaemia without mention of jaundice, not elsewhere classified

Primary outcomes

1

Description

Neonatal jaundice

Timepoint

0,24,48,72 hour

Method of measurement

Bilirubin detection kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: recipient of probiotic drops along with phototherapy, daily recipient of 6 drops of probiotics from Rotfeld company

Category

Rehabilitation

2

Description

Control group: Infants receiving phototherapy as a routine treatment for jaundice

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Hospital in Urmia

Full name of responsible person

nasim khalili dizaji

Street address

Urmia, Resalat Boulevard, Emergency Alley

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Postal code

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Phone

+98 914 414 2718

Email

nasimkhalilidizaji@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

کامران دهقان

Street address

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Email

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Nasim khalili dizaji

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Kamran Dehghan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Email

nasimkhalilidizaji@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Nasim khalili dizaji

Position

Student

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

Individual data can be shared after being unidentified

When the data will become available and for how long

Access started after 1401

To whom data/document is available

Researchers working in institutions

Under which criteria data/document could be used

Type of analysis

From where data/document is obtainable

Dr. Nasim Khalili

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

Please provide me with probiotic data

Comments