

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Sinbiotics (Prebiotics and Probiotics) with standard phototherapy on treatment of neonatal hyperbilirubinemia with 2-14 days of age in compare with standard phototherapy

Protocol summary

Summary

Purpose: Assessment of Sinbiotic's effect (Probiotic and Prebiotic) on treatment of neonatal hyperbilirubinemia with 2-14 days of age. Design: This Study is a Randomized clinical trial. Population of the study: Neonates admitted in neonatal section of Sabzevar's Heshmatie Hospital with bilirubin level more than 15 mg/dl with 2 to 14 days of age. Inclusion criteria: Neonates with 2 to 14 days of age; Neonates with serum bilirubin level more than 15 mg/dl and direct bilirubin less than 1.5 mg/dl; Neonates with normal retic count. Exclusion criteria: Neonates with low Hemoglobin and positive Glucose-6- Phosphate Dehydrogenase (G6PD) and direct Coombs. Volume of samples: In each group- control and intervention 40 neonates altogether 80 neonates enter the study. Study intervention: Control group treat with photo therapy in 3 days but in intervention group in addition to 3 days photo therapy, Sinbiotic (Probiotic and Prebiotic) like Pedilact 5 drops each day (equivalent 109 CFU of Lactobacillus reuteri, Lactobacillus rhamnosus and Bifidobacterium infantis stubs) untill 3 days have given, then serum bilirubin level checked in 1, 2 and 3 days and have recorded and then compared with control group. Intervention date: From February 11 until March 13 2017. results: If the effect of Sinbiotic has proved, we can use these products to treat neonatal Jaundice faster and reduce time of admission and economic costs and prevent from dangerous Jaundice adverse effect like Kernicterus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041933523N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Sorur Yari

Name of organization / entity

Sabzevar University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2017-02-11, 1395/11/23

Expected recruitment end date

2017-03-13, 1395/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Sinbiotics (Prebiotics and Probiotics) with standard phototherapy on treatment of neonatal hyperbilirubinemia with 2-14 days of age in compare with standard phototherapy

Public title

Effect of Sinbiotic on faster treatment of neonatal jaundice

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Neonates with 2 to 14 days of age; Neonates with serum bilirubin level more than 15 milligrams per deciliter (mg/dl) and direct bilirubin less than 1.5 mg/dl; Neonates with normal retic count; Neonates do not have Cephalohematoma and Caputsuccedaneum; Neonates with more than 37 weeks gestational age; Neonates with more than 2500 grams birth weight; Neonates without Polycythemia (Hematocrit more than 65); Neonates without past medical history; Neonates without blood exchange. Exclusion criteria: Neonates with low Hemoglobin and positive Glucose-6-Phosphate Dehydrogenase (G6PD) and Direct Coombs; Neonates that have Cephalohematoma and Caputsuccedaneum; Neonates that their parents do not have satisfaction; Neonates that receive serum therapy, Antibiotic therapy and Intravenous Immunoglobulin (IVIG) therapy; Neonates that have abnormal Peripheral Blood Smear (PBS).

Age
From **2 days** old to **14 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

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

Sabzevar University of Medical Science

Street address

Central construction of Sabzevar University of Medical Science, Asadabadi street, Sabzevar, Iran

City

Sabzevar

Postal code

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.MEDSAB.REC.1395.110

Health conditions studied

1

Description of health condition studied

Neonatal Jaundice

ICD-10 code

p59.9

ICD-10 code description

Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description

Level of serum bilirubin

Timepoint

One, 2 and 3 days after treatment

Method of measurement

Milligram per Deciliter with laboratorial study of neonates' blood

Secondary outcomes

empty

Intervention groups

1

Description

In control group neonates treat with photo therapy in 3 days. Neonates treat with 8 lamps photo therapy systems of Tusan brand using TL 20W/52 lamps with 425-475 Nanometer (nm) wavelength and 20-25 centimeters distance for 24 hours in one day for 3 consecutive days. Then neonates' blood samples have given in 1, 2 and 3 dayes of treatment and serum bilirubin compare with intervention group.

Category

Treatment - Other

2

Description

In intervention group in addition to 3 days photo therapy, Sinbiotic (Probiotic and Prerbiotic) like Pedilact oral drop 5 drops each days (equivalent 109 Colony Forming Units (CFU) of Lactobacillus reuteri, Lactobacillus rhamnosus and Bifidobacterium infantis stubs) untill 3 days have given them. Neonates treat with 8 lamps photo therapy systems of Tusan brand using TL 20W/52 lamps with 425-475 Nanometer (nm) wavelength and 20-25 centimeters distance for 24 hours in one day for 3 consecutive days. Then neonates' blood samples have given in 1, 2 and 3 dayes of treatment and serum

bilirubin compare with control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar's Heshmatie Hospital

Full name of responsible person

Sorur Yari

Street address

Sabzevar's Heshmatie Hospital, Asadabadi Street,
Sabzevar, Iran

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Science

Full name of responsible person

Sorur Yari

Street address

Central Building, Asadabadi Street, Sabzevar, Iran

City

Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Science

Full name of responsible person

Sorur Yari

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Perofessor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

Medical Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty