

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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

+98 21 7733 0416

###### Email address

www.yaris1@medsab.ac.ir

##### 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**

**Street address**

Central building, Asadabadi Street, Sabzevar, Iran

**City**

Sabzevar

**Postal code**

**Phone**

+98 51 4401 1000

**Fax**

**Email**

www.soruryari1991@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Science

**Full name of responsible person**

Dr Mitra Aldaghi

**Position**

Perofessor

**Other areas of specialty/work**

**Street address**

Asadabadi street, Sabzevar, Iran

**City**

Sabzevar

**Postal code**

**Phone**

+98 51 4401 1000

**Fax**

**Email**

yasaminiran2000@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Science

**Full name of responsible person**

Sorur Yari

**Position**

Medical Student

**Other areas of specialty/work**

**Street address**

Asadabadi street, Sabzevar, Iran

**City**

Sabzevar

**Postal code**

**Phone**

+98 51 4401 1000

**Fax**

**Email**

www.soruryari1991@yahoo.com

**Web page address**

**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*