

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of probiotics effects on bilirubin level in patient with neonatal jaundice admitted in the hospital

Protocol summary

Summary

In this study, The term infants with neonatal jaundice given the lack of criteria for inclusion and exclusion criteria, by an assistant collaborator fall under examination. In view of the fact that the bilirubin level is the same in both groups. Both groups of babies aged less than 10 days. The length of stay in the neonatal ward considers in the judgment, and the average weight and bilirubin was recorded babies Newborn randomly (limited) in two groups (probiotic drops) and control group (distilled water) divided. Infants in the study group (treated), receive about 5 drops probiotics 3 times a day + phototherapy and control group instead of a drop probiotics, distilled water + phototherapy. Defecation in the first and fourth day, are reported by Mother and nurse. The level of total serum bilirubin during the four consecutive days once venous sampling and testing methods biochemistry, measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061018974N3**

Registration date: **2017-07-25, 1396/05/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

Simin Gheini

Name of organization / entity

Kermanshah University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research, kermanshah university of Medical Sciences

Expected recruitment start date

2016-08-23, 1395/06/02

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of probiotics effects on bilirubin level in patient with neonatal jaundice admitted in the hospital

Public title

Evaluation of probiotics effects on bilirubin level

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term infants with age between 3-10 days and gestational age of 42-37 weeks, birth weight equals or more than 2500 g, and bilirubin 12.9-up mg / dL at the start of phototherapy, and fed only by breast milk. Exclusion criteria: infants with blood disorders family, having signs of hemolysis due to blood group incompatibility, internal bleeding indoors due to complications of traumatic birth (exp: cephalohematoma), suspected neonatal infection such as chorioamnionitis, intrauterine infection, sepsis and

urinary tract infection, perinatal hypoxic newborns, having thyroid dysfunction, distress or respiratory failure, malfunction regulate body temperature and metabolic, hemodynamic instability and congenital heart disease, a history of maternal use of phenobarbital during the last month of pregnancy venous hematocrit 65%

Age

From **1 day** old to **10 days** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

no

Secondary trial Id

no

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee kermanshah university of medical sciences

Street address

kermanshah shahid behashti Blv number 2 building

City

kermanshah

Postal code

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

IR.KUMS.REC.1396.85

Health conditions studied

1

Description of health condition studied

neonatal hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

P59.9 Neonatal jaundice, unspecified Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description

bilirubin level

Timepoint

from 1 to 4 days

Method of measurement

serum bilirubin level

Secondary outcomes

1

Description

defecations times

Timepoint

1 and 4 days

Method of measurement

mother report

Intervention groups

1

Description

Infants in the study group(treated)receive,about 5 drops probiotics 3 times a day + phototherapy probiotic is included Lactobacillus rhamnosus - Lactobacillus reuteri - Bifidobacterium infant. Drops are produced in Iran by iran Takhmer company, and are licensed in England conventional phototherapy :6 lamp photo mark PHilips TL 20/120 made in germany in 35 cm from patient.

Category

Treatment - Drugs

2

Description

control group: Distilled water 5 drops/3 times day+phototherapy Distilled waters are produced by shahid ghazi in 2 cc package conventional phototherapy :6 lamp photo mark PHilips TL 20/120 made in Germany in 35 cm from patient

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

mohamad kermanshahi hospital

Full name of responsible person

simin gheini

Street address

mohamad kermanshahi hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy Minister for Research and Technology

Full name of responsible person

DR Hamzie

Street address

kermanshah shahid behashti Blv number 2 building

City

kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy Minister for Research and Technology

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

kermanshah university of medical sceinces

Full name of responsible person

simin gheini

Position

pediatrictriction

Other areas of specialty/work**Street address**

Mohamad kermanshahi Hospital

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Person responsible for updating data

Contact

Name of organization / entity

kermanshah university of medical sceinces

Full name of responsible person

simin gheini

Position

MD

Other areas of specialty/work**Street address**

Mohamad kermanshahi Hospital

City

Kermanshah

Postal code**Phone**

00

Fax**Email****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

