Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Summary

In this studt,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 judgmeit, and the average weight and bilirubin was recorded babies Ne.wborn 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

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Simin Gheini
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Kermanshah University Of Medical Sciences
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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 : cephalohematom), 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 sceinces

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 lilirubin 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 infanti. Drops are produced in Iran by iran Takhmer company, and are licensed in England conventional photitherapy :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
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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

Data Dictionary	*empty*