

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of probiotic with phototherapy in compare to phototherapy for treatment of hyperbilirubinemia in fullterm infants

Protocol summary

Summary

Subject: Efficacy of probiotic with phototherapy in compare to phototherapy for treatment of hyperbilirubinemia in fullterm neonates admitted to shahid Madani hospital in Khorramabad inclusion criteria: gestational age 37-40 weeks; birth weight 2500-4000 gram; apgar score 8-10 in first and fifth minute. exclusion criteria: sepsis; G6PD deficiency; congenital anomaly; asphyxia; heart disease ;IUGR; contraindication for probiotic therapy. Volume:35 neonates in each group. Interventions: neonates would be divided into two groups as intervention and control. Control group are treated with phototherapy as routine therapy and the next group is treated with phototherapy and probiotic 5 drops orally every day. Serum bilirubin would be checked every day until it receives to less than 11mg/dl and neonate be discharged. Time: 22.12.2015 to 21.05.2016. Primary outcome: bilirubin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112925287N1**
Registration date: **2015-12-18, 1394/09/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-18, 1394/09/27

Registrant information

Name

Shokufe Ahmadipour

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3341 1439

Email address

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of probiotic with phototherapy in compare to phototherapy for treatment of hyperbilirubinemia in fullterm infants

Public title

Efficacy of probiotic in jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: gestational age 37-40 weeks; birth weight 2500-4000 gram; apgar score 8-10 in first and fifth minute. exclusion criteria: sepsis; G6PD deficiency; congenital anomaly; asphyxia; heart disease ;IUGR; contraindication for probiotic therapy.

Age

From **2 days** old to **7 days** old

Gender

Both

Phase

N/A

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**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Lorestan University of Medical Sciences

Street address

Kamalvand campus, Khorramabad

City

Khorramabad

Postal code**Approval date**

2015-09-01, 1394/06/10

Ethics committee reference number

LUMS.REC.1394.17

Health conditions studied**1****Description of health condition studied**

hyperbilirubinemia

ICD-10 code

p59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes**1****Description**

bilirubin

Timepoint

before intervention-every day after intervention

Method of measurement

lab test-milligram per desiliter

Secondary outcomes**1****Description**

weight

Timepoint

before intervention-every day after intervention

Method of measurement

balance-gram

Intervention groups**1****Description**

intervention group: in addition to phototherapy neonates will be treated by 5 drops of probiotic (pedilact) once a day till discharge.

Category

Treatment - Drugs

2**Description**

control group: during hospitalization only receive phototherapy

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

shahid Madani hospital

Full name of responsible person

dr Shokufe Ahmadi-pour

Street address**City**

Khorramabad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Lorestan University of Medical Sciences

Full name of responsible person

dr Morovat Taheri kalani

Street address

research center

City

Khorramabad

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

Yes

Title of funding source
Lorestan University of Medical Sciences
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
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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