Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Univercity 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 Ahmadipour
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
Lorestan University of Medical Sciences
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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