

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of probiotics with phototherapy in compare to phototherapy for reduction of bilirubin in term neonates

Protocol summary

Summary

To evaluate the impact of probiotics on serum bilirubin we give pedilavt drop to 150neonate. We include who is term, healthy and weigh more than 2500 gram and exclude whom has blood group incompatibility, Rh incompatibility and G6PD deficiency and other risk factods. Study group is given pedilact drop 10 drop per day plus phototherapy and control group is given only phototherapy. serum bilirubin level is taken at admission, 24, 48 and 72 hours later and number of admission days will be record and then results will be compared to determin the impact of probiotics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032333129N1**

Registration date: **2017-05-30, 1396/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

Abes Ahmadi Jazi

Name of organization / entity

Babol University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 2151

Email address

abes.ahmadi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Science

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotics with phototherapy in compare to phototherapy for reduction of bilirubin in term neonates

Public title

Effect of probiotics on treating neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : term; healthy; age less than 28 day and more than 1day; weight more than 2500 grams;

Exclusion criteria : ABO incompatibility; Rh incompatibility; G6PD deficiency, weight below 2500 gr; history of exchange transfusion in previous sibling; use of drugs such as Phenobarbital during pregnancy; drug and home remedy for jaundice; gestational age less than 37 completed weeks;

Age

To 30 days old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**
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
Babol University of Medical Science
Street address
Keshavarz boulevard
City
Babol
Postal code
Approval date
2016-12-24, 1395/10/04
Ethics committee reference number
MUBABOL.HRI.REC.1395.80

Health conditions studied

1

Description of health condition studied

Neonatal jaundice
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified:Physiological jaundice
(intense)(prolonged) NOS

Primary outcomes

1

Description

Serum billirubin level in study group
Timepoint
At admission serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

2

Description

Serum billirubin level in study group
Timepoint

Second day serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

3

Description

Serum billirubin level in study group
Timepoint
Third day serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

4

Description

Serum billirubin level in study group
Timepoint
Forth day serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

5

Description

Serum billirubin level in contrl group
Timepoint
At admission serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

6

Description

Serum billirubin level in contrl group
Timepoint
Second day serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

7

Description

Serum billirubin level in contrl group
Timepoint
Third day serum billirubin
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

8

Description

Serum billirubin level in contrl group
Timepoint
Forth day serum billirubin level
Method of measurement
mg/dl , device: bilitest A from tajhizat sanjesh company

Secondary outcomes

1

Description

Duration of admission in control group

Timepoint

At discharge

Method of measurement

Day

2

Description

Need of blood exchange transfusion in control group

Timepoint

At discharge

Method of measurement

No

3

Description

Need of blood exchange transfusion in control group

Timepoint

At discharge

Method of measurement

Yes

4

Description

Need of blood exchange transfusion in study group

Timepoint

At discharge

Method of measurement

No

5

Description

Duration of admission in study group

Timepoint

At discharge

Method of measurement

Day

6

Description

Need of blood exchange transfusion in study group

Timepoint

At discharge

Method of measurement

Yes

Intervention groups

1

Description

Administration of probiotics to study group Pedilact drop from Zist Takhmir Company 10 drop/day

Category

Treatment - Drugs

2

Description

control group is given only phototherapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Children's Hospital

Full name of responsible person

Dr Abes Ahmadi Jazi

Street address

Amirkola Emam Boulevard

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Science

Full name of responsible person

Mrs Moslem Nejad

Street address

Keshavarz boulevard

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

Babol University of Medical Science

Full name of responsible person

Dr Abes Ahmadi Jazi

Position

Fellowship resident of neonatology

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Science

Full name of responsible person

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Position

Neonatalogist

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Babol University of Medical Science

Full name of responsible person

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Position

Fellowship resident of neonatalogy

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

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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