

# 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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**Postal code****Phone**

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Abesahmadijazi@yahoo.com

**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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**Fax****Email**

Zypasha@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Science

**Full name of responsible person**

Dr Abes Ahmadi Jazi

**Position**

Fellowship resident of neonatalogy

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**Postal code****Phone**

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Abesahmadijazi@yahoo.com

**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*