

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of phototherapy on serum 25(OH) vitamin D level in neonatal hyperbilirubinemia

#### Protocol summary

##### Study aim

The effect of phototherapy on serum 25 hydroxyvitamin D levels in neonatal hyperbilirubinemia

##### Design

All the newborns with an age of more than 72 hours that had been referred to Amirkola Children's Hospital (ACH) with serum bilirubin level more than 15mg/dl have been considered as the case group and received phototherapy according to the ACH phototherapy protocol. Bilirubin was checked by spectrophotometry method by chemical kits and serum 25(OH) vitamin D level was checked by ELISA; in two times before phototherapy and 72 hours after the start of phototherapy. The primary consequences: Determination of serum 25(OH) vitamin D levels. The secondary consequence: Determination of serum bilirubin level that would be compared before and after the intervention.

##### Settings and conduct

All the newborns with an age of more than 72 hours that had been referred to Amirkola Children's Hospital (ACH)

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Term infants (weight: 2500–4000 g) who required phototherapy, Infant From 3 day old to 28 days old Exclusion Criteria: Infants with congenital anomalies Asphyxia prenatal (birth, APGAR score less than 4 at 1 minute or less than 7 at 5 minutes of birth, Incidence of clinical signs of sepsis or blood cultures during phototherapy, the need for blood transfusions during the study, Incidence clinical benefit of Kernicterus

##### Intervention groups

Get a phototherapy at a distance of 20 centimeters from the body surface

##### Main outcome variables

serum 25 hydroxyvitamin D levels

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180925041133N1**

Registration date: **2018-10-08, 1397/07/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-08, 1397/07/16**

Update count: **0**

##### Registration date

2018-10-08, 1397/07/16

##### Registrant information

###### Name

Yadollah Zahedpasha

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3234 2151

###### Email address

y.zahedpasha@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of phototherapy on serum 25(OH) vitamin D level in neonatal hyperbilirubinemia

##### Public title

The effect of phototherapy on serum vitamin D level in neonatal hyperbilirubinemia

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Term infants (weight: 2500–4000 g) who required phototherapy From 3 day old to 28 days old

#### **Exclusion criteria:**

Infants with congenital anomalies Asphyxia prenatal (birth, APGAR score less than 4 at 1 minute or less than 7 at 5 minutes of birth Incidence of clinical signs of sepsis or blood cultures during phototherapy The need for blood transfusions during the study Incidence clinical benefit of Kern icterus

### **Age**

From **3 days** old to **28 days** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

##### **Street address**

Daneshgah Square, Ganjafrooz Avenue

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

45745-47176

#### **Approval date**

2018-09-18, 1397/06/27

#### **Ethics committee reference number**

IR.MUBABOL.HRI.REC.1397.134

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Neonatal Hyperbilirubinemia

#### **ICD-10 code**

P59.9

#### **ICD-10 code description**

Neonatal jaundice, unspecified

## **Primary outcomes**

### 1

#### **Description**

25(OH) vitamin D

#### **Timepoint**

Before phototherapy and 72 hours after the start of phototherapy

#### **Method of measurement**

ELISA - ng/ml

## **Secondary outcomes**

### 1

#### **Description**

Bilirubine level

#### **Timepoint**

at admission, phototherapy, discharge time

#### **Method of measurement**

Measuring of the total serum bilirubin level by biochemistry kits manufactured in Iran and by the method of spectrophotometry.

## **Intervention groups**

### 1

#### **Description**

Infants received phototherapy at a distance of 20 centimeters from the body surface. Bilirubin was checked by spectrophotometry method by chemical kits and serum 25(OH) vitamin D level was checked by ELISA; in two times before phototherapy and 72 hours after the start of phototherapy

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Amirkola Children's Hospital

##### **Full name of responsible person**

Yadollah Zahedpasha

##### **Street address**

No 19, Amirkola Children's Hospital, Amirkola, Babol,

Mazandaran Province, IR Iran.

**City**

Amirkola, Babol

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**Postal code**

4731741151

**Phone**

+98 11 3234 6963

**Email**

y.zahedpasha@mubabol.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

**Street address**

Babol university Of medical seinces, University square  
, Babol

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**Phone**

+98 11 3219 9595

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rezaghadimi@yahoo.com

**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 Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Yadollah Zahedpasha

**Position**

Full professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr Mousa Ahmadpour-Kacho

**Position**

Full professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Babol University of Medical Sciences

**Full name of responsible person**

Yadollah Zahedpasha

**Position**

Full professor

**Latest degree**

Subspecialist

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available