

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of oral zinc administered on the bilirubin serum level in the icterus mature newborns

#### Protocol summary

##### Summary

Purpose: Evaluation of the effect oral zinc on the serum bilirubin levels in term neonates. 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. On the other hand newborns with serum bilirubin level more than 15mg/dl have been considered as control group. In both groups phototherapy were done according to the ACH phototherapy protocol. Bilirubin was checked by spectrophotometry method by chemical kits and serum zinc level was checked by auto analyzer; in two times before the photo therapy start and at the discharge time. By choosing 30 cases in the each group it would be possible to detect the effect of one unit differences between the case and control group, with 95 percent confidence interval and 80 percent ability test. The study is double blinded; study phases are trial 1 and 2 done in one center (Amirkola Children's Hospital). Performed via a random number table. Inclusion criteria: Full term newborns, with of age for more than 72 hours and serum bilirubin level more than 15mg/dl. Exclusion criteria: All babies who received medication such as zinc sulphate and phenobarbital by mothers or newborn. Intervention: Oral zinc administration. The primary consequences: Determination of serum bilirubin level. The secondary consequence: detecting serum zinc levels that would be compared between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016072629077N1**

Registration date: **2017-03-16, 1395/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-16, 1395/12/26

##### Registrant information

###### Name

bahram ranjbar

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3234 6963

###### Email address

b.ranjbar@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Babol University of Medical Sciences

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of oral zinc administered on the bilirubin serum level in the icterus mature newborns

##### Public title

The effect of oral zinc administered on the bilirubin serum level in the icteric mature newborns

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Full term newborns; with of age for more than 72 hours & serum bilirubin level more than 15 mg/dl. Exclusion criteria: All babies who received medication such as zinc sulphate & phenobarbital by mothers or newborn

## Age

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

## Gender

Both

## Phase

1-2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

-

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Babol University of Medical Sciences Ethics Committee

##### Street address

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran Babol

##### City

Babol

##### Postal code

4717647745

#### Approval date

2016-08-22, 1395/06/01

#### Ethics committee reference number

MUBABOL,HRI.REC.1395.27

## Health conditions studied

### 1

#### Description of health condition studied

Hyperbilirubinemia

#### ICD-10 code

P59.9

#### ICD-10 code description

Physiological jaundice (intense)(prolonged) NOS

## Primary outcomes

### 1

#### Description

Serum bilirubin's level

#### Timepoint

Total serum bilirubin level at the time of admission, daily during the hospitalization and at the time of the discharge

#### Method of measurement

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

## Secondary outcomes

### 1

#### Description

Serum zinc's level

#### Timepoint

At the time of admission and discharge

#### Method of measurement

Auto analyser

## Intervention groups

### 1

#### Description

Administration of 5mg of zinc sulfate BD/per day in the treatment group

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirkola Children's Hospital

##### Full name of responsible person

Dr Bahram Ranjbar

##### Street address

No 19, Amirkola Children's Hospital, Amirkola, Babol, Mazandaran Province, IR Iran.

##### City

Amirkola, Babol

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice- Chancellor for Research Technology Affairs,  
Babol University of Medical Sciences

**Full name of responsible person**

Dr Ali Akbar Moghaddamnia

**Street address**

Vice- Chancellor for Research Technology Affairs,  
Babol University of Medical Sciences, Ganjafroz  
Street, Babol, Mazandaran Province, IR Iran

**City**

Babol

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice- Chancellor for Research Technology Affairs, Babol  
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**

Amirkola Children's Hospital

**Full name of responsible person**

Dr Bahram Ranjbar

**Position**

Pediatrician

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

No 19, Amirkola Children's Hospital, Amirkola, Babol,  
Mazandaran Province, Iran

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Amirkola Children's Hospital

**Full name of responsible person**

Dr Mousa ahmadpour-Kacho

**Position**

Neonatologist

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

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## Person responsible for updating data

**Contact****Name of organization / entity**

Amirkola Children's Hospital

**Full name of responsible person**

Dr Bahram Ranjbar

**Position**

Pediatrician

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

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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*