

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of oral zinc on hyperbilirubinemia on LBW premature neonates admitted in NICU

#### Protocol summary

##### Summary

The goal of this study was to evaluate the effect of zinc sulfate in the treatment of jaundice in low birth weight newborns. In a randomized double blind placebo - controlled study, low birth weight infants with the complaint of icter are selected. Study participants receive either zinc sulfate 10 mg BID as per oral for 5 days or placebo twice time/ day for five Dayes. Then they receive phototherapy and their bilirubin level is measured in 12hr, 24hr, 48hr, 72hr, 96hr and 120 hour afterword.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201401041162N22**  
Registration date: **2015-07-31, 1394/05/09**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-31, 1394/05/09

##### Registrant information

###### Name

Ashraf Mohammadzadeh

###### Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1852 1121

###### Email address

mohamadzadeha@mums.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-05-24, 1393/03/03

##### Expected recruitment end date

2015-06-18, 1394/03/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of oral zinc on hyperbilirubinemia on LBW premature neonates admitted in NICU

##### Public title

Effect of oral zinc on hyperbilirubinemia on LBW premature neonates admitted in NICU

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Babies who admitted to NICU of Imam Reza Hospital; birth weight 1500-2500 gm; Exclusion Criteria: jaundice in day one; hemolysis with positive comb's test; severely ill babies; infection and sepsis based on clinical and lab test; those with ventilator support; five minutes apgar less than 7; congenital anomalies; intolerance of feeding ; intolerance of zinc supplementation ( gastrointestinal hemorrhage and residue, suddenly getting poor general condition) ; and mothers with sing of high or low level of serum zinc

##### Age

From **2 days** old to **28 days** old

##### Gender

Both

##### Phase

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

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice chancellor for research of Mashad University of  
Medical Sciences

##### Street address

Ghoreshi bilding, Daneshgah street

##### City

Mashhad

##### Postal code

#### Approval date

2014-05-24, 1393/03/03

#### Ethics committee reference number

922234

## Health conditions studied

### 1

#### Description of health condition studied

low birth weight

#### ICD-10 code

P07.1

#### ICD-10 code description

Other low birth weight

### 2

#### Description of health condition studied

hyperbilirubinemia

#### ICD-10 code

P59.0

#### ICD-10 code description

Neonatal jaundice associated with preterm delivery

## Primary outcomes

### 1

#### Description

decreasing of serum bilirubin

#### Timepoint

befor intervention and 12,24,48,72 , 96 and 120 hours  
after intervention

#### Method of measurement

measurment of serum bilirubin (diazo method)

## Secondary outcomes

### 1

#### Description

teratment of jaundice of neonate

#### Timepoint

befor intervention and 24,48,72 , 96 and 120 hours after  
intervention

#### Method of measurement

decreasing of jaundice and bilirubin level in blood serum

## Intervention groups

### 1

#### Description

in cases: zinc sulfate 10 mg BID as per oral for 5 days or  
placebo twice time/ day

#### Category

Treatment - Drugs

### 2

#### Description

in controls:Placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

NICU Imam Reza Hospital , Neonatal Research Center

##### Full name of responsible person

Dr Ashraf Mohammadzadeh

##### Street address

NRC, NICU, Imam Reza Hospital

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

**Street address**

Gghoreshi bulding, Daneshgah street

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Neonatal Research Center

**Full name of responsible person**

Dr Ashraf Mohammadzadeh

**Position**

Neonatologist, professor

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

NRC, NICU, Imam Reza Hospital

**City**

Mashhad

**Postal code****Phone**

+98 51 1852 1121

**Fax****Email**

mohamadzadeha@mums.ac.ir

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

Neonatal Research Center

**Full name of responsible person**

Dr Ashraf Mohammadzadeh

**Position**

Neonatologist, professor

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

NRC, NICU, Imam Reza Hospital

**City**

Mashhad

**Postal code****Phone**

+98 51 1852 1121

**Fax****Email**

mohamadzadeha@mums.ac.ir

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

Neonatal Research Center

**Full name of responsible person**

Dr Ashraf Mohammadzadeh

**Position**

Neonatologist, professor

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

NRC, NICU, Imam Reza Hospital

**City**

Mashhad

**Postal code****Phone**

+98 51 1852 1121

**Fax****Email**

mohamadzadeha@mums.ac.ir

**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*