

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

tereatment 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

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+98 51 1852 1121

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Full name of responsible person

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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