

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Prophylactic Effect of oral zinc on hyperbilirubinemia in premature very low birth weight neonates who admitted in NICU

Protocol summary

Summary

The aim of this study was to determine the prophylactic effect of zinc sulfate in very low birth weight (birth weight < 1500 gm) infants' hyperbilirubinemia. In a randomized double blind clinical trial 60 very low birth weight infants will elect. Those babies who will admit to NICU as including and infants with 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 such as gastrointestinal hemorrhage and residue, suddenly getting poor general condition and mothers with singe of high or low level of serum zinc will exclude. Study participants receive 10mg zinc sulfate twice a day from day 2 (zinc sulfate group n=30), the other group will receive sterile water as volume as zinc sulfate (control group n=30) by Orogastric tube. As preterm baby need zinc sulfate as supplement in discharge , zinc sulfate will continue as maintenance dose in case group. Serum bilirubin levels will measure at entrance, day 3, day 5 and day 7. Duration of phototherapy also will record in two groups. Side effects drug will observe by physical exam.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306081162N20**

Registration date: **2013-07-09, 1392/04/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-09, 1392/04/18

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 science

Expected recruitment start date

2013-04-17, 1392/01/28

Expected recruitment end date

2014-05-18, 1393/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic Effect of oral zinc on hyperbilirubinemia in premature very low birth weight neonates who admitted in NICU

Public title

Prophylactic Effect of oral zinc on hyperbilirubinemia in premature very low birth weight neonates who admitted in NICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Babies who admitted to NICU of Imam

Reza Hospital; birth weight $\leq$ 1500 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 years** old to **2 years** old

Gender

Both

Phase

4

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**

2013-05-25, 1392/03/04

Ethics committee reference number

910825

Health conditions studied**1****Description of health condition studied**

very low birth weigh hyperbilirubinemia

ICD-10 code

P59.0

ICD-10 code description

Neonatal jaundice associated with preterm delivery

Primary outcomes**1****Description**

serum bilirubin

Timepoint

befor intervention, day 3, day 5 and day 7

Method of measurement

measurment of serum bilirubin (diazot method)

Secondary outcomes**1****Description**

jaundice

Timepoint

befor intervention,day 3, day 5 and day 7

Method of measurement

decreasing of jaundice

Intervention groups**1****Description**

For intervention: 10mg zinc sulfate twice a day since birth and will continue to4000 gr postnatal weight per oral

Category

Treatment - Drugs

2**Description**

Foe control: the placebo such as case group which prepared by Pharmacologist

Category

Treatment - Drugs

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

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Web page address

Person responsible for updating data

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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