

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Efficacy of zinc sulfate in reducing unconjugated hyperbilirubinemia in premature neonate in NICU

Protocol summary

Summary

The purpose is efficacy of zinc sulfate in reducing unconjugated hyperbilirubinemia in premature neonate. It's a randomized, double blinded and controlled with placebo study. Inclusion criteria: premature neonate with GA 30-37 week/weight 1500-2500 exclusion criteria: hemolysis or sepsis, abnormality, dehydration, G6PD, ABO mismatch, positive coombs, history of consumption phenobarbital by mother, IUGR, ventilation, NPO. We have 2 groups: zinc sulfate and placebo. All of neonates will be treated with phototherapy. Neonates in sulfate group will receive 1mg/kg zinc sulfate more than photo. In other group neonates will receive 1mg/kg placebo more than photo. Prescription is oral with syringe and every 6 hours until the end of phototherapy. Measurement of the level of bilirubin is the beginning of admission then 6 hours after that and then daily. Target sample size is 60.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120825439N1**
Registration date: **2016-02-21, 1394/12/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-21, 1394/12/02

Registrant information

Name

Seyyedeh Hoda Khatib Masjedi

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3604 3228

Email address

hodakhatib@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of zinc sulfate in reducing unconjugated hyperbilirubinemia in premature neonate in NICU

Public title

Efficacy of zinc sulfate in icter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: premature neonate with GA 30-37 week; weight 1500-2500 exclusion criteria: hemolysis; sepsis; abnormality; dehydration; G6PD; ABO mismatch; positive coombs; history of consumption phenobarbital by mother; IUGR; ventilation; NPO

Age

To **1 month** old

Gender

Both

Phase

N/A

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**

Birjand University of Medical Sciences

Street address

ghafari avenue

City

Birjand

Postal code

9717853577

Approval date

2015-10-31, 1394/08/09

Ethics committee reference number

ir.bums.1394.51

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

indirect hyperbilirubinemia

ICD-10 code

P59.0

ICD-10 code description

Neonatal jaundice associated with preterm delivery

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

level of bilirubin

Timepoint

6hours/24hours/48hours

Method of measurement

mg/dl

2**Description**

time of phototherapy

Timepoint

6hours/24hours/48hours

Method of measurement

hour

Secondary outcomes

empty

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

all of neonate will treat with phototherapy. neonate in sulfate group receive 1mg/kg (5mg/5cc) zinc sulfate more than photo. prescription is oral with syringe and every 6 hours until the end of phototherapy. measurement of the level of bilirubin is the beginning of admission then 6 hours after that and then daily

Category

Treatment - Drugs

2**Description**

In control group neonate will receive 1mg/kg placebo (sucrose) more than photo. prescription is oral with syringe and every 6 hours until the end of phototherapy. measurement of the level of bilirubin is the beginning of admission then 6 hours after that and then daily ,

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Dr Hoda Khatib

Street address**City**

Mashad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Reza Sharifzadeh

Street address

Ghafari aven
City
 Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Birjand University of Medica 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
 Birjand University of Medical Sciences
Full name of responsible person
 Gholamreza Faal
Position
 Specialty in Neonate
Other areas of specialty/work
Street address
 Valiasr Hospital
City
 Birjand
Postal code
Phone
 +98 56 3244 3005
Fax
Email
 grfal@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Birjand University of Medical Uciences
Full name of responsible person
 Gholam Reza Faal

Position
 specialty in neonate
Other areas of specialty/work
Street address
 Ghafari aveniue
City
 Birjand
Postal code
Phone
 +98 56 3244 3005
Fax
Email
 grfal@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 University of Medicine Scinese
Full name of responsible person
 Hoda Khatib Masjedi
Position
 Pediatric resident
Other areas of specialty/work
Street address
 Ghafari Avenue
City
 Birjand
Postal code
Phone
 +98 51 3604 3228
Fax
Email
 hmkhatib2772@yahoo.com
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