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 efficasy of zinc sulfate in reducing unconjugated hyperbilirubinemia in premature neonate.Its a randomized ,double blinded and controll with placebo study.Inclusion criteria:premature neonate with GA30-37week/weight1500-2500 exclusion criteria:hemolysis or sepsis,abnormality,dehydration,G6PD,ABOmissmatch,positive coombs,history of consumption phenobarbital by mother,IUGR,ventilation,NPO.we have 2 group:zinc sulfate and pacebo. all of neonate will treat with photothrapy.neonate in sulfate group reciecive 1mg/kg zincsulfate more than photo.in other group neonatewill recieve 1mg/kg placebo more than photo.prescription is oral with syrang and every 6 hours until the end of phototherapy.measurment of the level of bilirubin is the bigining 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

SeyyedehHoda 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 zincsulfate in icter

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:premature neonate with GA30-37week;weight1500-2500 exclusion criteria:hemolysis; o sepsis;abnormality;dehydration;G6PD;ABOmissmatch;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 aveniue
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 photothrapy.neonate in sulfate group reciecive 1mg/kg (5mg/5cc)zincsulfate more than photo.prescription is oral with syrang and every 6 hours until the end of phototherapy.measurment of the level of bilirubin is the bigining of admission then 6 hours after that and then daily
Category
Treatment - Drugs

2

Description
In control group neonatewill recieve 1mg/kg placebo(sucrose) more than photo.prescription is oral with syrang and every 6 hours until the end of phototherapy.measurment of the level of bilirubin is the bigining 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 Medica 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

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Fax

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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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

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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