Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of oral zinc sulfate in reduction of jaundice in term neonates

Protocol summary

Summary

The aim of this study was to determine the therapeutic effect of zinc sulfate in healthy term jaundiced neonates. Healthy jaundiced neonates, more than 38 th weeks gestational age, birth weight more than 2500 gr and indirect bilirubin in therapeutic level will elect. Exclusion criteria include: hemolytic disease, massive hemorrhage, G6PD deficiency, sepsis, respiratory distress with ventilator support, and congenital anomaly. Thirty five neonates (case group) will treat with a single oral dose of zinc sulfate as 2 cc daily plus phototherapy and another 35 neonates (control group)will receive only phototherapy. Zinc sulfate syrup includes 5 mgr in 1 ml, therefore the dose is 10mg daily. The plasma total bilirubin levels of 24th, 48th, 72th and 96th hours after treatment were measured .Duration of phototherapy also was recorded. Physical exam will control for drug side effect.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306031162N19**
Registration date: **2013-06-17, 1392/03/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-17, 1392/03/27

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

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Science

Expected recruitment start date

2013-05-15, 1392/02/25

Expected recruitment end date

2013-11-16, 1392/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral zinc sulfate in reduction of jaundice in term neonates

Public title

Effect of oral zinc sulfate in reduction of jaundice in term neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Healthy jaundiced neonates, more than 38 th weeks gestational age, birth weight more than 2500 gr and indirect bilirubin in therapeutic level Exclusion: hemolytic disease, massive hemorrhage, G6PD deficiency, sepsis, respiratory distress with ventilator support, and congenital anomaly

Age

From **3 years** old to **28 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

vice chanceler of mashhad university of medical science

Street address

ghoreshi bulding-daneshgah street

City

mashhad

Postal code

91379-13131

Approval date

2013-05-25, 1392/03/04

Ethics committee reference number

910894

Health conditions studied

1

Description of health condition studied

jaundice term newborns

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

decreasing serum bilirubine

Timepoint

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

Method of measurement

blood serum bilirobin(diazo method)

Secondary outcomes

1

Description

decreasing of jaundice in neonate

Timepoint

daily

Method of measurement

date of dissconection of potothorapy

2

Description

date of disconnection of phototrapy

Timepoint

daily

Method of measurement

decreasing of serum bilirobin below phototrapy level

Intervention groups

1

Description

zinc sulfate

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU Emamreza hospital and NICU Ghaem hospital

Full name of responsible person

dr.Ashraf mohammadzadeh

Street address

NRC-NICU-Emamreza hospital

City

mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

mashhad university of medical science

Full name of responsible person

dr Mohsen Tafaghodi

Street address

ghoreshi 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 science
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
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Person responsible for updating data

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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