Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of oral zinc sulfate on the reduction of bilirubin level term jaundiced neonates during phototherapy.

Protocol summary

Summary

The purpose of this clinical trial study that will be done in neonatal ward Shahid Madani hospital in Khorramabad city is to evaluate the effect of oral zinc sulfate on bilirubin level in healthy term neonates. The main inclusion criteria includes: Term newborns; Birth weight more than than 2500 grams; Without any signs of abnormalities and diseases (infectious, metabolic, hemolytic, glucose-six-phosphate dehydrogenase deficiency, blood group incompatibility and positive coombs test). The main exclusion criterion is the need for exchange transfusion. Newborns are assigned into two different groups with using blocked randomization: Control and treatment. The newborns in Control group will receive only continuous phototherapy; the treatment group in addition to continuous phototherapy will receive 5 mg of oral zinc sulfate twice a day. In both groups total bilirubin levels of serum will be measured at 24, 48, 72, and 96 hours after intervention. The main outcome of this study is to see the effect of oral zinc sulfate on the total bilirubin levels of serum. The duration of phototherapy will be recorded also in two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312067697N3**
Registration date: **2014-02-16, 1392/11/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-16, 1392/11/27

Registrant information

Name

Shourangiz Beiranvand

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Lorestan University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral zinc sulfate on the reduction of bilirubin level term jaundiced neonates during phototherapy.

Public title

The effect of oral zinc sulfate on the reduction of bilirubin level term jaundiced neonates during phototherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term neonates; Gestational age of 37-41 weeks; Birth weight more than 2500 grams; The minimum and maximum age of the infants between 3 - 28 days; Total bilirubin levels of Serum between 14 - 19 mg/dl; without any sign of abnormalities and diseases

(infectious, metabolic, hemolytic, glucose-six-phosphate dehydrogenase deficiency, blood group incompatibility and positive coombs test). Exclusion criteria: The need for exchange transfusion and intensive care for more than 24 hours.

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: **92**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be done by using blocked randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Department of Research and Technology, Lorestan University of Medical Sciences, Kamalvand

City
Khorramabad

Postal code
381351698

Approval date
2013-11-30, 1392/09/09

Ethics committee reference number
96196/200

Health conditions studied

1

Description of health condition studied
Neonatal Hyperbilirubinemia

ICD-10 code
P59.9

ICD-10 code description
Neonatal jaundice unspecified

Primary outcomes

1

Description
Total bilirubin levels of serum

Timepoint
Before intervention, 24, 48, 72 and 96 hours after intervention

Method of measurement
Measurement of serum total bilirubin (diazo method)

Secondary outcomes

1

Description
Duration of phototherapy

Timepoint
Daily

Method of measurement
Duration of phototherapy (days)

Intervention groups

1

Description
Intervention group: Newborns during continuous phototherapy will receive 5 mg of oral zinc sulfate twice a day.

Category
Treatment - Drugs

2

Description
Group control: Newborns only will receive continuous phototherapy.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madani Hospital

Full name of responsible person
Shourangiz Beiranvand

Street address
Nursing Department, Nursing and Midwifery Faculty, Lorestan University of Medical Sciences, Kamalvand

City
Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Lorestan University of Medical Sciences

Full name of responsible person
Mohammad Hassan Kaedi

Street address
Vice Chancellor for Research, Lorestan University of Medical Sciences, Kamalvand

City
Khorramabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research of Lorestan 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
Lorestan University of Medical Sciences

Full name of responsible person
Shourangiz Beiranvand

Position
Master of nursing, Faculty member of Lorestan University of Medical Sciences

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