

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)

Phone

+98 66 1330 5313

Email address

shorangiz.beiranvand@lums.ac.ir

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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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