

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of oral zinc sulfate on serum bilirubin level in term neonates with jaundice, a clinical trial

Protocol summary

Study aim

Determining the effect of oral zinc sulfate on serum bilirubin levels in term neonates

Design

This is a parallel randomized controlled clinical trial that will be performed on 128 infants with neonatal hyperbilirubinemia. Randomization in this research is done using blocks with size of 4 using syntax written in SPSS program. The duration of the study will be about 3 months.

Settings and conduct

This study is a clinical trial study with a control group that will be performed on a total of 128 infants referred to Bahar Shahroud Hospital. Patients' parents must sign an informed consent form before entering the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonates with a diagnosis of neonatal hyperbilirubinemia; Existence of indirect hyperbilirubinemia; Infants with a gestational age of 36 to 40 weeks; Birth weight more than 2500 grams; Stable vital signs; Informed consent of parents to participate in the research. Exclusion criteria: Apgar 5 minutes less than 5; Need for cardiopulmonary resuscitation; Presence of congenital heart, lung and liver malformations; Neonatal meningitis and TORCH infections.

Intervention groups

Patients included in the study are divided into two groups of intervention and control. In the intervention group, treatment with serum therapy, oxygen therapy, standard phototherapy with oral zinc sulfate at a rate of 1 ml per day will be performed. In the control group, treatment as in the intervention group will be prescribed with serum therapy, oxygen therapy and standard phototherapy without zinc sulfate.

Main outcome variables

Indirect bilirubin level and duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N23**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **prospective**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

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+98 23 3239 5054

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-29, 1399/09/09

Expected recruitment end date

2021-02-17, 1399/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral zinc sulfate on serum bilirubin level in term neonates with jaundice, a clinical trial

Public title

The effect of oral zinc sulfate on jaundice in term infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with a diagnosis of neonatal hyperbilirubinemia; Existence of indirect hyperbilirubinemia; Infants with a gestational age of 36 to 40 weeks; Birth weight more than 2500 grams; Stable vital signs; Informed consent of parents to participate in the research.

Exclusion criteria:

Apgar 5 minutes less than 5; Need for cardiopulmonary resuscitation; Presence of congenital heart, lung and liver malformations; Neonatal meningitis; TORCH infections.

Age

From **3 days** old to **15 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated to intervention and control groups according to random allocation table that illustrated by a statistician. Randomization was done using permuted block randomization method (Block size was 4) using blocked random allocation syntax in SPSS software. Sample size was 128. Study consisted of 32 blocks. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical

Sciences

Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

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Semnan

Postal code

3616647555

Approval date

2020-10-25, 1399/08/04

Ethics committee reference number

IR.SHMU.REC.1399.114

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.8

ICD-10 code description

Neonatal jaundice from other specified causes

Primary outcomes

1

Description

Indirect bilirubin level

Timepoint

Within 24, 48 and 72 hours of starting treatment

Method of measurement

Measurement of bilirubin by Diazo method

2

Description

Duration of hospitalization

Timepoint

On a daily basis from the start of treatment and hospitalization

Method of measurement

Day count from the medical records

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After initial and routine procedures including: hospitalization in the neonatal ward and serum therapy and oxygen therapy and stabilization of vital signs, standard photo therapy with oral sulfate at a rate of 1 ml per day will be prescribed.

Category

Treatment - Drugs

2

Description

Control group: For this group, as in the intervention group, only standard phototherapy will be prescribed, while performing initial and routine measures, including hospitalization in the neonatal ward, serum therapy, oxygen therapy, and stabilization of vital signs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Hospital of Shahroud

Full name of responsible person

Dr. Mahboobeh Mohammadi

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Bahar Hospital., End 22 Bahman street., Shahroud , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

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Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research; Shahroud University medical and Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Sahar Idrom

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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Full name of responsible person

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Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available