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
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Name of organization / entity
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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

City
Shahroud

Province
Semnan

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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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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