Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

Comparison of the Effect of Zinc-Sulfate Supplementation on the Treatment of Neonates with Hyperbilirubinemia: a Double-blind Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of zinc sulfate supplementation on the treatment of newborns with hyperbilirubinemia

Design

This double-blind randomized clinical trial study has an intervention group and a placebo group. The intervention group includes 140 newborns with hyperbilirubinemia who receive zinc sulfate orally at a daily dose of 1 mg per kilogram for 3 days. The placebo group includes 140 newborns with hyperbilirubinemia who receive 10% dextrose orally at a daily dose of 1 mg per kilogram of serum for 3 days. Randomization process: newborns will be completely randomly divided into two groups receiving zinc sulfate and placebo (10% dextrose serum). To perform randomization, Excel software uses the Random between command.

Settings and conduct

This study will be conducted in the neonatal department of Besat Hospital located in Sanandaj city, Kurdistan, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Term newborns with hyperbilirubinemia admitted to the neonatal department of Besat Hospital of Sanandaj in 2022, gestational age from 37 weeks to 42 weeks and 6 days, birth weight from 2500 gr to 4000 gr Exclusion criteria: Evidence of infection, congenital malformation, history of phenobarbital use, hypothyroidism, intrauterine growth restriction, oral intolerance, mechanical ventilation

Intervention groups

Intervention group: The group receiving zinc sulfate medicine at a dose of 1 mg per kilogram once a day Placebo group: The group receiving 10% dextrose serum at a dose of 1 mg per kilogram once a day

Main outcome variables

Average serum total bilirubin 24 hours, 48 hours and 72 hours after intervention in two groups Average serum indirect bilirubin 24 hours, 48 hours and 72 hours after intervention in two groups The mean changes in serum total bilirubin between before the intervention and 24, 48 and 72 hours after the intervention for two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220806055625N1**
Registration date: **2022-12-25, 1401/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-25, 1401/10/04**
Update count: **0**

Registration date

2022-12-25, 1401/10/04

Registrant information

Name

Siros Hemmatpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 7751

Email address

dr.siroshemmatour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Zinc-Sulfate Supplementation on the Treatment of Neonates with Hyperbilirubinemia: a Double-blind Randomized Clinical Trial

Public title

Investigating the effect of Zinc-Sulfate on the Treatment of Neonatal Hyperbilirubinemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term infants with hyperbilirubinemia admitted to the neonatal department of Besat Sanandaj Hospital in 1401
Gestational age from 37 weeks to 42 weeks and 6 days
Birth weight from 2500 Grams to 4000 Grams

Exclusion criteria:

Evidence of infection Congenital malformation History of phenobarbital use in mother Hypothyroidism Inappropriate intrauterine growth Oral intolerance Mechanical ventilation

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **250**

Randomization (investigator's opinion)

Randomized

Randomization description

Neonates will be completely randomly assigned to two groups receiving Zinc- Sulfate and placebo (10% Dextrose serum). To perform randomization, Excel software is used with the Random between command. To carry out this process, a two-digit code is assigned to each of the people entered into the study, and then using the software, these numbers are randomly selected to enter each of the groups. Odd or even numbers will be assigned to one group each.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the design is double-blind; so that the neonates studied in two groups and their families and clinical caregivers are blinded to the intervention and intervention status. Medicines are stored in dark bottles labeled A and B and given using a dropper.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Str. Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

661776796

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.MUK.REC.1400.322

Health conditions studied

1

Description of health condition studied

Neonatal Hyperbilirubinemia

ICD-10 code

P58

ICD-10 code description

Neonatal jaundice due to other excessive hemolysis

Primary outcomes

1

Description

Mean serum total bilirubin

Timepoint

Serum total bilirubin 24 hours, 48 hours and 72 hours after intervention in two groups

Method of measurement

taking blood samples from the infants in the study at 24 hours, 48 hours and 72 hours after the intervention by a trained nurse and sending them to the lab

2

Description

Mean serum indirect bilirubin

Timepoint

serum indirect bilirubin 24 hours, 48 hours and 72 hours after intervention in two groups

Method of measurement

taking blood samples from the infants in the study at 24 hours, 48 hours and 72 hours after the intervention by a trained nurse and sending them to the lab

3

Description
The amount of changes in the mean serum total bilirubin
Timepoint
Before the intervention and 24 hours after the intervention
Method of measurement
comparing the average total serum bilirubin before the intervention and the average total serum bilirubin obtained 24 hours after the intervention.

4

Description
The amount of changes in the mean serum total bilirubin
Timepoint
Before the intervention and 48 hours after the intervention
Method of measurement
comparing the average total serum bilirubin before the intervention and the average total serum bilirubin obtained 48 hours after the intervention.

5

Description
The amount of changes in the mean serum total bilirubin
Timepoint
Before the intervention and 72 hours after the intervention
Method of measurement
comparing the average total serum bilirubin before the intervention and the average total serum bilirubin obtained 72 hours after the intervention.

Secondary outcomes

1

Description
The average number of hospitalization days of newborns in two groups
Timepoint
Number of hospitalization days 24 hours, 48 hours and 72 hours after intervention in two groups
Method of measurement
Registration the number of hospitalization days of the newborns according to the file by a trained nurse

2

Description
The average hours of receiving phototherapy for newborns in two groups
Timepoint
Number of hours receiving phototherapy 24 hours, 48 hours and 72 hours after intervention in two groups
Method of measurement
Registering data of number of hours receiving phototherapy by a trained nurse

3

Description
Possible complications of zinc sulfate drug
Timepoint
24 hours, 48 hours and 72 hours after the intervention in two groups
Method of measurement
A booklet containing the desired questions related to possible complications (these complications are selected by reviewing the literature) is provided to the mothers of babies and is followed up by a trained nurse.

Intervention groups

1

Description
Intervention group: 125 infants will be placed in the group receiving zinc sulfate orally at a dose of 1 mg per kilogram once a day, on the first, second and third days of the intervention. According to Harriet Lane's book, which is one of the authoritative references for infants and children, the recommended dose of zinc sulfate for infants is 1 mg per kilogram per day, which is the same amount prescribed for infants in the intervention group.
Category
Treatment - Drugs

2

Description
Control group: 125 infants are placed in the group receiving 10% dextrose serum orally on the first, second and third days of the intervention. Dextrose serum at the rate of one milligram per kilogram once a day is administered to infants in the control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Sirus Hematpour
Street address
Keshavarz Street
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3328 5911

Email
Info@muk.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
Street address
Abidar Ave., Sanandaj
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6618634683
Phone
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Email
Info@muk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj University of Medical Sciences
Proportion provided by this source
1
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
Sanandaj University of Medical Sciences
Full name of responsible person
Sirous Hematpour
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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