Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Oral Zinc Supplementation on Serum Bilirubin Reduction in Hospitalized Neonates with Jaundice in Mofid and Mahdieh Hospitals: A Randomized Double-Blind Clinical Trial

Protocol summary

Study aim

Effect of oral zinc supplementation on reducing serum bilirubin levels in neonates with hyperbilirubinemia admitted to Mofid and Mahdieh Children's Hospitals.

Design

This study will be conducted as a randomized controlled clinical trial, with a double-blind, placebo-controlled, parallel-group design. This phase III trial will be performed on 100 term and near-term neonates with indirect neonatal hyperbilirubinemia.

Settings and conduct

The study will be conducted in the neonatal units of Mofid and Mahdieh Children's Hospitals. Neonates will be randomly allocated to intervention and control groups. The intervention group will receive standard care plus oral zinc (10 mg/day), while the control group will receive standard care plus a placebo. Total serum bilirubin (TSB) will be measured at baseline and at 6, 12, 24, 48, 72, and 96 hours after intervention in both groups.

Participants/Inclusion and exclusion criteria

Term and near-term neonates (gestational age ≥35 weeks) hospitalized with indirect hyperbilirubinemia requiring phototherapy, adequate oral feeding tolerance, and written parental consent were included in the study. Neonates with early-onset jaundice (<24 hours), sepsis, need for mechanical ventilation, major congenital anomalies, gastrointestinal disorders, requirement for exchange transfusion, or evidence of hemolysis were excluded.

Intervention groups

Neonates in the intervention group will receive standard care plus oral zinc (10 mg/day), while the control group will receive standard care plus a matched placebo. Standard treatment includes phototherapy, adequate feeding, and routine clinical and vital sign monitoring, with identical phototherapy devices and standardized settings in both groups.

Main outcome variables

Total serum bilirubin (TSB) level at 48 hours after initiation of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260627069958N1**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **prospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

Registration date

2026-07-09, 1405/04/18

Registrant information

Name

Sadaf Bahramian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Oral Zinc Supplementation on Serum Bilirubin Reduction in Hospitalized Neonates with Jaundice in Mofid and Mahdieh Hospitals: A Randomized Double-Blind Clinical Trial

Public title
Effect of Oral Zinc Supplementation on Serum Bilirubin Reduction in Neonates with Jaundice
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Neonates diagnosed with indirect neonatal hyperbilirubinemia requiring phototherapy, as determined by the treating physician according to established institutional guidelines. Neonates with a gestational age of 35–42 weeks. Initiation of enteral feeding with adequate tolerance of oral feeding. Written informed consent from the parents or legal guardian before enrollment.
Exclusion criteria:
Jaundice presentation within the first 24 hours of life. Development of sepsis, severe systemic illness, or hemodynamic instability. Requirement for mechanical ventilation. Presence of major congenital anomalies or known genetic syndromes. Concomitant administration of any medication or dietary supplement with a potential bilirubin-lowering effect. Feeding intolerance, recurrent vomiting, or gastrointestinal disorders that could interfere with supplement administration. Requirement for exchange transfusion at enrollment or during the initial hours of hospitalization before completion of the study protocol. Evidence of hemolysis. Withdrawal of parental or legal guardian consent at any stage of the study.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
To ensure balanced group sizes throughout the enrollment process, block randomization with a fixed block size of four will be used. Neonates will be randomized in blocks of four. Randomization will be stratified by sex and baseline total serum bilirubin level (<18 mg/dL and ≥18 mg/dL) to ensure a balanced distribution of the initial severity of hyperbilirubinemia between the intervention and control groups. The random allocation sequence will be generated by an independent individual who is not involved in the study using Random Allocation Software. Allocation assignments will be placed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. Upon enrollment of each eligible neonate, the next envelope in the predetermined sequence will be opened, and only the designated pharmacist responsible for preparing the study intervention will be informed of the treatment assignment. The individual responsible for generating the randomization sequence and maintaining the allocation envelopes will have no involvement in participant recruitment, clinical management, outcome assessment, data collection, or statistical analysis.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind clinical trial. The parents or legal guardians of the neonates, as well as all members of the research team, including the treating physicians, ward nurses, the researcher responsible for data collection, the outcome assessor, and the statistician, will remain blinded to group allocation throughout the study. Only the designated pharmacist responsible for preparing the study intervention will be aware of the allocation codes. The allocation codes will remain concealed until completion of the final statistical analysis, unless emergency unblinding is required due to a serious adverse event or when knowledge of the treatment assignment is deemed necessary for appropriate clinical management.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Sixth Floor, Building No. 2, Shahid Beheshti University of Medical Sciences, Tehran, Yemen Street, Arabi Street, Shahid Chamran Highway, Tehran, Iran.
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Province
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Postal code
1985717443
Approval date
2026-06-16, 1405/03/26
Ethics committee reference number
IR.SBMU.MSP.REC.1405.185

Health conditions studied

1

Description of health condition studied
Neonatal jaundice
ICD-10 code
P59.3
ICD-10 code description
Neonatal jaundice from breast milk inhibitor

Primary outcomes

1

Description
The primary outcome will be total serum bilirubin (TSB) level at 48 hours after initiation of the intervention.
Timepoint
48 hours after initiation of the intervention
Method of measurement
Neonatal bilirubin level in this study will be measured as total serum bilirubin using a venous blood sample and standard laboratory biochemical analysis (photometric bilirubinometry) performed in the hospital laboratory.

Secondary outcomes

1

Description
Total serum bilirubin (TSB) level at 12 hours after initiation of the intervention
Timepoint
12 hours after initiation of the intervention
Method of measurement
Neonatal bilirubin level in this study will be measured as total serum bilirubin using a venous blood sample and standard laboratory biochemical analysis (photometric bilirubinometry) performed in the hospital laboratory.

2

Description
Total serum bilirubin (TSB) level at 24 hours after initiation of the intervention
Timepoint
24 hours after initiation of the intervention
Method of measurement
Neonatal bilirubin level in this study will be measured as total serum bilirubin using a venous blood sample and standard laboratory biochemical analysis (photometric bilirubinometry) performed in the hospital laboratory.

3

Description
Mean duration of phototherapy (hours).
Timepoint
Measurement of time in hours from the actual initiation of the device to its complete discontinuation.
Method of measurement
Measurement of time in hours from the actual initiation of the device to its complete discontinuation.

4

Description
Mean length of hospital stay (days)
Timepoint
Measurement of hospital stay duration from admission to discharge
Method of measurement
Measurement of hospital stay duration from admission to discharge

Intervention groups

1

Description
Intervention group: In the intervention group, neonates will receive standard treatment plus oral zinc supplementation at a dose of 10 mg/day. Standard neonatal jaundice care will include phototherapy, adequate feeding, and routine monitoring of vital signs and clinical status. Phototherapy devices and settings will be identical in both groups according to the unit protocol.
Category
Treatment - Drugs

2

Description
Control group: In the control group, neonates will receive standard care plus a placebo identical in appearance, volume, color, and packaging. Standard neonatal jaundice management will include phototherapy, adequate feeding, and routine monitoring of vital signs and clinical assessment. Phototherapy devices and settings will be identical in both groups according to the unit protocol.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of neonatology at Mofid Children's Hospital
Full name of responsible person
Minou Fallahi
Street address

Dr. Shariati Ave, Mofid Children's Hospital, Tehran, Iran.

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2

Recruitment center

Name of recruitment center
Department of neonatology at Mahdieh Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Minou Fallahi

Position
Professor of Neonatology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Position
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Subspecialist

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Person responsible for updating data

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Name of organization / entity

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data collected during the study will be de-identified and made available for data sharing.

When the data will become available and for how long

The de-identified study data will be available for sharing upon submission of the manuscript derived from this study to a peer-reviewed journal.

To whom data/document is available

Access to the de-identified study data will be available to all interested readers.

Under which criteria data/document could be used

The complete de-identified dataset may be used for pooled analyses or meta-analyses upon reasonable request to the corresponding author and with the necessary approval.

From where data/document is obtainable

Vahide Zeinali, email: v.zeinali4183@sbmu.ac.ir

What processes are involved for a request to access data/document

Upon publication of the study, a public electronic link to the de-identified dataset will be provided. During the publication process (before online publication), researchers may request access to the data by contacting the corresponding author via email and providing the purpose and details of their request. Subject to approval by the research team, the requested data will be shared within 24 hours.

Comments