Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of Zinc Sulfate during the duration of the need for Phototherapy in infants with Congenital Jaundice

Protocol summary

Study aim
Investigating the simultaneous effect of phototherapy with oral zinc sulfate on the amount of bilirubin change in babies with hyperbilirubinemia and the duration of their treatment.

Design
The study group are infants without risk factors, which were divided into 2 groups "phototherapy with zinc sulfate" and "phototherapy alonely" based on the sample size of 120 people and randomization by means of boxes of 4 people, and the study was conducted in a double-blind manner, will be done.

Settings and conduct
The method of conducting the study is double-blind, which is carried out in the Neonatal and Neonatal Intensive Care Unit of Baharlou Hospital with the blinding of the ward nurse and the parents of the hospitalized baby. The blinding of the study is done by dividing the babies into 4 boxes and determining the intervention for each baby based on the available possibilities and based on rolling the dice which has 6 states, based on which the baby is given zinc sulfate syrup or sucrose.

Participants/Inclusion and exclusion criteria
The criteria for the inclusion of infants in the study include all infants with indirect hyperbilirubinemia with pathological total bilirubin levels for age and time of birth. The criteria for the exclusion of infants from the study include those that can affect the result of the study as a confounding factor; For example, liver diseases and all diseases that affect the level of bilirubin, or babies who take supplements containing zinc.

Intervention groups
The studied intervention is zinc sulfate (syrup 5 mg per 5 cc), which is administered orally at the rate of 1 mg per kilogram of the baby's body weight for 48 hours.

Main outcome variables
The amount of time and frequency required to perform phototherapy if zinc sulfate is prescribed for infants.

General information

Reason for update
Updating sample number and study duration

Acronym

IRCT registration information
IRCT registration number: **IRCT20230914059430N1**
Registration date: **2024-01-29, 1402/11/09**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **1**

Registration date
2024-01-29, 1402/11/09

Registrant information

Name
Asghar Ghorbani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 912 321 1189

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aghorbani@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date
2024-08-22, 1403/06/01

Actual recruitment end date
2025-11-22, 1404/09/01

Trial completion date
2025-11-22, 1404/09/01

Scientific title
Investigating the effectiveness of Zinc Sulfate during the duration of the need for Phototherapy in infants with Congenital Jaundice

Public title
Investigating the simultaneous effect of Phototherapy with oral Zinc Sulfate on the amount of Bilirubin change in infants with Hyperbilirubinemia and the duration of their treatment in Baharlou Hospital.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All infants without risk factors born with Neonatal Jaundice
Exclusion criteria:
Lack of parental consent The presence of major risk factors in the baby, including Cardiovascular, Pulmonary, Renal defects, etc.

Age
From **1 day** old to **14 days** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **320**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization of the study is done in groups of 4 babies in one box, and according to the 2 possible interventions, 6 modes are considered for these boxes, and the status of each box is determined by throwing a dice.

Blinding (investigator's opinion)
Double blinded

Blinding description
The mentioned randomization is carried out by the researcher.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Science
Street address
Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1936893813

Approval date
2024-01-21, 1402/11/01

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.575

Health conditions studied

1

Description of health condition studied
Congenital Jaundice

ICD-10 code
P59

ICD-10 code description
Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description
Total Bilirubin

Timepoint
Measurement of serum total bilirubin level at the beginning of the study (before the start of the intervention), 24, 48 and 72 hours after the start of oral zinc sulfate intake.

Method of measurement
Blood examination

Secondary outcomes

1

Description
The duration of receiving phototherapy

Timepoint
Up to 14 days after the study

Method of measurement
Medical record

2

Description
The length of hospitalization

Timepoint
Up to 14 days after the study

Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: Receiving oral zinc sulfate syrup 1 cc/kg, each 5 cc containing 5 mg of zinc while performing phototherapy, which is prescribed for 48 hours.
Category
Treatment - Drugs

2

Description
Control group: Receiving Phototherapy alonely
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharlou Hospital
Full name of responsible person
Asghar Ghorbani
Street address
Behdari St., Rahahan Sq., Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Corner of Qods St., Keshavarz Blvd., Tehran, Iran.
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Phone
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Email
vcr@sina.tums.ac.ir
Web page address
https://vcr.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Asghar Ghorbani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All potential data can be shared after de-identifying individuals after contacting the corresponding author.

When the data will become available and for how long
The beginning of the access period from 2026

To whom data/document is available
Researchers, Doctors and Health Decision Makers

Under which criteria data/document could be used
If any data is not reported in the text of the final report and the addressee needs it, this information will be provided to the requester if it is not about the confidential information of the patients.

From where data/document is obtainable
The manager Dr. Ghorbani

What processes are involved for a request to access data/document
Contact the project manager

Comments