Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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 full-term infants without risk factors, which were divided into 2 groups "phototherapy with zinc sulfate" and "phototherapy with placebo" based on the sample size of 320 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 full-term 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, which is administered orally at the rate of 1 cc per kilogram of the baby's body weight for 48 hours. The placebo intervention is sucrose syrup at the rate of 1 cc per kilogram of the baby's body weight.

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

Acronym

IRCT registration information

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

Last update: **2024-01-29, 1402/11/09**
Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Asghar Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 321 1189

Email address

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

empty

Actual recruitment end date

empty

Trial completion date
empty

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 full-term babies 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**

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 and also the solutions used in both interventions are similar in terms of color, smell and taste.

Placebo
Used

Assignment
Parallel

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), 2 and 14 days after the start of oral zinc sulfate intake.

Method of measurement
Blood examination

2

Description
Zinc Sulfate level in serum

Timepoint
Immediately before and after phototherapy depending on the duration of phototherapy

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 cc containing 1 mg of zinc while performing phototherapy, which is checked for 48 hours.
Category
Treatment - Drugs

2

Description
Control group: Receiving a placebo of sucrose syrup with a concentration of 1cc/kg while performing phototherapy
Category
Placebo

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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https://baharloo.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
Street address
Corner of Qods St., Keshavarz Blvd., Tehran, Iran.
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Tehran
Postal code
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Phone
+98 21 8163 3685
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