Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of Oral Calcium Gluconate Effect on Serum Bilirubin Levels in Late Preterm Neonates Admitted to the Neonatal Intensive Care Unit of Vali-Asr Hospital in 2026

Protocol summary

Study aim

Determining the Effect of Oral Calcium Gluconate on Serum Bilirubin Levels in Late Preterm Neonates Admitted to the Neonatal Intensive Care Unit of Valiasr Hospital

Design

This study will be conducted as a single-blind, randomized, parallel-group clinical trial on 62 neonates (31 neonates in each of the intervention and control groups). Randomization will be performed using the Block Randomization method.

Settings and conduct

This study will be conducted on late preterm neonates admitted to the Neonatal Intensive Care Unit as a single-blind trial (with blinding of the researchers responsible for data analysis) involving 62 neonates (31 neonates in each group). the intervention group will receive oral calcium gluconate in addition to standard phototherapy.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Late preterm neonates with a gestational age of 34 to 36 weeks and 6 days who have indirect (unconjugated) hyperbilirubinemia and are admitted to the Neonatal Intensive Care Unit of Valiasr Hospital. Exclusion Criteria: Neonates who do not meet the inclusion criteria. In addition, any neonate who develops complications during the study will be withdrawn from the study.

Intervention groups

All neonates enrolled in the study will receive standard phototherapy according to the hospital protocols under the supervision of a neonatologist. In addition to standard phototherapy, oral calcium gluconate will be administered at a dose of 50 mg/kg of body weight per day, divided into four equal doses (every 6 hours). The calcium gluconate ampoules will be prepared as a solution by the investigator and provided to the nursing staff for the purpose of this study. Administration will continue until the resolution of jaundice and discontinuation of phototherapy.

Main outcome variables

Serum indirect bilirubin level, Serum calcium level, Duration of phototherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260802070508N1**
Registration date: **2026-10-30, 1405/08/08**
Registration timing: **prospective**

Last update: **2026-10-30, 1405/08/08**
Update count: **0**

Registration date

2026-10-30, 1405/08/08

Registrant information

Name

Sara Khademi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-05-19, 1406/02/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Oral Calcium Gluconate Effect on Serum Bilirubin Levels in Late Preterm Neonates Admitted to the Neonatal Intensive Care Unit of Vali-Asr Hospital in 2026

Public title
Evaluation of Oral Calcium Gluconate Effect on Serum Bilirubin Levels in Late Preterm Neonates Admitted to the Neonatal Intensive Care Unit of Vali-Asr Hospital in 2026
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Late preterm neonates (34–36 weeks and 6 days of gestation) diagnosed with indirect hyperbilirubinemia requiring phototherapy, who meet all of the following conditions:Absence of clinical instability No evidence of sepsis Not currently intubated No clinical or laboratory evidence of infection or hemolysis No contraindication to oral medication (not NPO) No prior treatment with calcium before initiation of phototherapy (for hypocalcemia or total parenteral nutrition) Serum calcium level ≤10 mg/dL at the time of initiation of phototherapy No maternal history of opioid addiction No maternal use of anticonvulsant medications No maternal hyperparathyroidism Absence of any congenital anomalies Parental consent for participation in the study
Exclusion criteria:
Unstable clinical condition Sepsis Intubation Clinical or laboratory evidence of infection or hemolysis Contraindication to oral medication Calcium therapy before initiation of phototherapy due to hypocalcemia or total parenteral nutrition (TPN) Serum calcium level >10 mg/dL at the initiation of phototherapy Maternal opioid addiction Maternal use of anticonvulsant medications Maternal hyperparathyroidism Presence of any congenital anomaly Parental refusal to participate in the study
Age
To **30 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **62**
More than 1 sample in each individual
Number of samples in each individual: **6**
Complete Blood Count (CBC), Total and Direct Serum Bilirubin (TSB & Direct), Serum Calcium (total), Serum AlbuminBlood Group and Rh, Direct Coombs Test, Reticulocyte Count, Peripheral Blood Smear (PBS), Glucose-6-Phosphate Dehydrogenase (G6PD assay)
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be employed for participant allocation. This method is used to ensure a relative balance in the number of participants between the two groups throughout the enrollment process. Generation of Random Numbers and Group Allocation: 1. Block Size Determination: The block size will be predefined; in this study, a block size of four will be used. This means that within each block, four neonates will be randomly allocated to the two groups. 2. Generation of Permutation Blocks: For each block, all possible permutations of participant allocation to the groups will be generated (in this case, two participants in the intervention group and two in the control group). For a block size of four, the possible permutations are: AABB, ABAB, ABBA, BAAB, BABA, and BBAA (A: intervention group; B: control group). 3. Random Selection of Blocks: The permutation blocks will be randomly selected, and their sequence will also be randomized. For example, a possible random sequence may be: BABA, AABB, BBAA, ABAB, and so on. 4. Participant Allocation: As each eligible neonate is enrolled, allocation will be performed according to the predefined randomized block sequence. For example, the first neonate may be assigned to group B (control), the second to group A (intervention), the third to group B, and the fourth to group A. Upon completion of the first block, allocation will proceed with the next randomly ordered block. 5. Use of Software or Random Number Tables: The generation of random blocks and participant allocation will be conducted using statistical software (such as R, Stata, or Excel) or standard random number tables with a predefined algorithm to ensure complete allocation concealment and minimize selection bias.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the nature of the intervention, namely the oral administration of calcium gluconate, which is readily identifiable, complete double blinding of the patients and the clinical care team directly involved in the management of the neonates will not be feasible. However, to the extent possible, the researchers responsible for statistical data analysis will remain blinded to the allocation of neonates to the intervention and control groups (single blinding). This will be achieved by coding the data and separating group allocation information from the primary dataset to minimize potential bias in the analysis of the results. Since the study outcomes will be assessed using quantitative and standardized methods, the absence of complete blinding is not expected to result in substantial bias.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences, Ghaffari Blvd., Birjand, South Khorasan, Iran

City
Birjand

Province
South Khorasan

Postal code
۹۷۱۷۸۵۳۰۷۶

Approval date
2026-07-28, 1405/05/06

Ethics committee reference number
IR.BUMS.REC.1405.146

Health conditions studied

1

Description of health condition studied
Indirect (unconjugated) hyperbilirubinemia

ICD-10 code
P59.0

ICD-10 code description
Neonatal jaundice associated with preterm delivery

Primary outcomes

1

Description
Changes in serum levels of indirect (unconjugated) bilirubin

Timepoint
At baseline (admission),12, 24, 48, and 72 hours after the start of treatment, and at the final assessment

Method of measurement
Blood sample

2

Description
Duration of phototherapy requirement

Timepoint
At baseline (admission),12, 24, 48, and 72 hours after the start of treatment, and at the final assessment

Method of measurement
Based on the serum bilirubin level until it decreases to 2 units below the phototherapy threshold

Secondary outcomes

1

Description
Serum calcium level

Timepoint
At baseline (admission), 12, 24, 48, and 72 hours after the start of treatment, and at the final assessment.

Method of measurement
Blood sample

2

Description
Rate of decrease in indirect (unconjugated) bilirubin

Timepoint
At baseline (admission), 12, 24, 48, and 72 hours after the start of treatment, and at the final assessment.

Method of measurement
Blood sample

Intervention groups

1

Description
Intervention group: The intervention group consists of 31 late preterm neonates with jaundice (icterus) who, in addition to standard treatment (phototherapy), will receive oral calcium gluconate at a dose of 50 mg per kg of body weight per day, divided into four equal doses.

Category
Treatment - Drugs

2

Description
Control group: The control group consisted of 31 late preterm neonates with jaundice who received standard treatment for unconjugated hyperbilirubinemia (phototherapy).

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Sara Khademi

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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
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Gholamreza Faal
Position
Associate Professor
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Subspecialist
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Person responsible for updating data

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Latest degree
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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
This dataset includes demographic data, laboratory results (total and direct bilirubin, total calcium, albumin, CBC, blood group, direct Coombs test, reticulocyte count, G6PD assay, and peripheral blood smear) at baseline, 12, 24, 48, and 72 hours, as well as the final assessment, total duration of phototherapy, and information on possible adverse events. The data are provided in anonymized form after coding and removal of direct identifiers (name, medical record number, etc.).
When the data will become available and for how long
Data will be available starting 6 months after the publication of the final article resulting from this study and will remain accessible for a period of 5 years.
To whom data/document is available
Access is restricted to researchers affiliated with recognized academic institutions, research centers, and scientific organizations who submit a written and justified request.
Under which criteria data/document could be used
The data may be used solely for scientific research purposes, including verification of the original study results, meta-analyses, or secondary analyses related to neonatal hyperbilirubinemia and the effect of calcium supplementation. Commercial use, redistribution of the raw data without prior written permission from the principal investigator, and any attempt to re-identify participants are strictly prohibited.
From where data/document is obtainable
Contact by phone or submit a written request via email to the Vice-Chancellor for Research of Birjand University of Medical Sciences: Email: research@bums.ac.ir Phone: 056-32381200
What processes are involved for a request to access data/document
The applicant submits a written request, including an explanation of the research purpose, their full personal details, and institutional affiliation, via email to the Vice-Chancellor for Research of Birjand University of Medical Sciences. After reviewing the reason for the data access request, the data will be provided to the researcher.
Comments