Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Evaluation of total serum magnesium concentrations in neonatal hyperbilirubinemia before and after phototherapy

Protocol summary

Summary

Background& Objectives: Binding indirect bilirubin to the neuronal membranes receptors such as N-methyl-Daspartate causes permanent injuries. Magnesium (Mg) ion is proposed to be one of the most important antagonistic regulators of this receptor. We aim to investigate the relationship between serum levels of total magnesium and bilirubin before and after phototherapy in term neonates. It can help to find new therapeutic and management techniques and the best time for discharge. Design&Setting: In this semi-experimental, we study icteric neonates admitted to Zahedan Imam Ali hospital from March 2009 to March 2010. Inclusion criteria: 90 otherwise-healthy term newborns with nonhemolytic hyperbilirubinemia during the first 4 weeks of life according to their age and standard graphs Exclusion criteria: Those neonates with anemia(Hb<8); symptoms in favor of hemolysis (ABO or Rh mismatch, G6PD deficiency, positive direct coombs test); history of Mg sulfate administration in mother and symptoms and signs in favor of infections; metabolic or endocrine disorders. Intervention& outcome: After complete physical examination, venous blood samples when indicated will be taken for the laboratory characteristics. Hyperbilirubinemia severity groups will be mild (14-16 mg per dL), moderate (16-18 mg per dL), and severe (≥18 mg per dL) respectively. After necessary recommendations phototherapy will be applied for the breast-fed newborns with exaggerated bilirubin concentrations and those for whom initial interventions could not decline their elevating bilirubin levels. Forty-eight hours after phototherapy, the same measurement for tMg and total serum bilirubin will be performed.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015090823942N1**
Registration date: **2016-03-22, 1395/01/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-22, 1395/01/03

Registrant information

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Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Zahedan University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2011-03-06, 1389/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of total serum magnesium concentrations in neonatal hyperbilirubinemia before and after

phototherapy

Public title
Total serum magnesium in the icteric neonates before and after phototherapy
Purpose
Screening
Inclusion/Exclusion criteria
Inclusion criteria: 90 otherwise-healthy term newborns with nonhemolytic hyperbilirubinemia during the first 4 weeks of life according to their age and standard graphs Exclusion criteria:Those neonates with anemia(Hb<8); symptoms in favor of hemolysis (ABO or Rh mismatch, G6PD deficiency, positive direct coombs test); history of Mg sulfate administration in mother and symptoms/signs in favor of infections; metabolic and endocrine disorders
Age
From **1 day** old to **15 days** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
To investigate total plasma levels of magnesium (tMg) in neonatal hyperbilirubinemia; before and after phototherapy serum bilirubin and plasma tMg will be measured in 90 otherwise-healthy term newborns with nonhemolytic hyperbilirubinemia

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee with supervision of Vice-chancellor for Research of Zahedan University of Medical S
Street address
Hesabi sq.
City
Zahedan
Postal code
98167-43463
Approval date
2010-10-20, 1389/07/28
Ethics committee reference number
IR.ZAUMS.REC.1389.2134

Health conditions studied

1

Description of health condition studied
Neonatal jaundice
ICD-10 code
P59.9
ICD-10 code description
Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description
Total serum bilirubin
Timepoint
Before and after phototherapy
Method of measurement
Spectrophotometry

Secondary outcomes

1

Description
Total serum magnesium
Timepoint
Before and after phototherapy
Method of measurement
Atomic absorption

Intervention groups

1

Description
Intervention group: The breast-fed newborns with exaggerated Bilirubin levels and those for whom initial managements could not decline increasing Bilirubin loads, phototherapy was employed based on the neonates' age and Bilirubin levels.Forty-eight hours after phototherapy, the same measurement for tMg and total Serum Bilirubin was performed.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan Imam Ali hospital
Full name of responsible person
Mahmood Rezaee-pour
Street address
City
Zahedan

2

Recruitment center
Name of recruitment center
Aliasghar Pediatrics hospital
Full name of responsible person
Mehdi Shiri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research of Zahedan University of Medical Sciences
Full name of responsible person
Mahmood Imani
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Hesabi Sq.
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Grant name
Grant code / Reference number
447/ت
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research of Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty