

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

Name

Mehdi Shiri

Name of organization / entity

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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

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Hesabi sq.

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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

Street address**City**

Tehran

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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Grant name**Grant code / Reference number**

447/ب

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

Contact

Name of organization / entity

Razi hospital, Department of Dermatology, Tehran University of Medical Sciences

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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*