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

Update count: 0
Registration date
2016-03-22, 1395/01/03

Registrant information
Name
Mehdi Shiri
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 5560 9951
Email address
m_shiri@razi.tums.ac.ir

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

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

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

Description of health condition studied
Neonatal jaundice

ICD-10 code
P59.9

ICD-10 code description
Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

Description
Total serum bilirubin

Timepoint
Before and after phototherapy

Method of measurement
Spectrophotometry

Secondary outcomes

Description
Total serum magnesium

Timepoint
Before and after phototherapy

Method of measurement
Atomic absorption

Intervention groups

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

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
Street address
Hesabi Sq.
City
Zahedan
Grant name
Grant code / Reference number
447/
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
Full name of responsible person
Mehdi Shiri
Position
M.D.
Other areas of specialty/work
Street address
Vahdat_e_eslami st.
City
Tehran
Postal code
1199663911
Phone
+98 21 5560 9951
Fax
Email
msh.iuems@gmail.com
Web page address
www.tums.ac.ir/razi

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Pediatrics, Zahedan University of Medical Sciences
Full name of responsible person
Mahmood Rezaee-pour
Position
M.D.
Other areas of specialty/work
Street address
HESABI SQ.
City
Zahedan
Postal code
Phone
+98 54 3341 6703
Fax
Email
m.rezaypoor48@yahoo.com
Web page address
http://www.zaums.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Razi hospital, Department of Dermatology, Tehran University of Medical Sciences
Full name of responsible person
Mehdi Shiri
Position
M.D.
Other areas of specialty/work
Street address
Vahdat_e_eslami st.
City
Tehran
Postal code
1199663911
Phone
+98 21 5560 9951
Fax
Email
msh.iuems@gmail.com
Web page address
www.tums.ac.ir/razi
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