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-D-aspartate 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

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

Last update:
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

**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**
Zahedan Imam Ali hospital

**Full name of responsible person**
Mahmood Rezaee-pour

**Street address**
City
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
empty

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.iums@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
1199663911
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.iums@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