Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Head covering during phototherapy appropriate and safe method for Prevention of phototherapy-induced hypocalcaemia in icterus newborn with unaltered serum magnesium level.

Protocol summary

Summary

Objectives: The aim of the present investigation was to study the effect of hat on calcium and magnesium levels in full term newborns during phototherapy. Design: In this randomized clinical trial, 72 icterus newborns with indirect hyperbillirubinemia who received phototherapy in phototherapy ward of Moslemin Hospital in Shiraz province of Iran from March to September 2010 were studied randomly in two groups. Setting and Conduct: Phototherapy was conducted in the control group, while was performed with hat for the test group. Participants including major eligibility criteria: They were full term and weighted more than 2500 gr. Apart from icterus; indirect bilirubin between 13 to 18 mg/dl in full term neonates - their physical status was completely normal. The newborns were in perfect health during the tests. Newborns with asphyxia; respiratory distress; sepsis; hemolytic anemia; infants of mothers with diabetic or thyroid disorders was excluded from study. Intervention: The calcium and magnesium levels of each newborn were tested on arrival, 48 hours after phototherapy, and 24 hours following phototherapy. Main outcome measure variables: Billirubin, calcium and Magnesium

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102315134N1**
Registration date: **2014-01-08, 1392/10/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-01-08, 1392/10/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Deputy chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Head covering during phototherapy appropriate and safe method for Prevention of phototherapy-induced hypocalcaemia in icterus newborn with unaltered serum magnesium level.

Public title

Head covering effects on serm calcium during phototherapy

Purpose

Prevention

Inclusion/Exclusion criteria
The major including criteria were : Full term; Weighed more than 2500 grams; Had normal serum calcium; Apart from icterus; indirect bilirubin between13 to 18 mg/dl in full term neonates - their physical status was completely normal. The major excluding criteria were: Asphyxia; respiratory distress; sepsis; hemolytic anemia; infants of mothers with diabetic or thyroid disorders.

Age
From **3 years** old to **5 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
7 floor, Shiraz University of Medical Sciences building, Zand street

City
Shiraz

Postal code
73452-46372

Approval date
2010-11-21, 1389/08/30

Ethics committee reference number
89-5313

Health conditions studied

1

Description of health condition studied
Jaundice

ICD-10 code
p50 , p51

ICD-10 code description
Haemorrhagic and haematological disorders of fetus and newborn

Primary outcomes

1

Description
Bilirubin

Timepoint
The bilirubin level of each newborn were tested on arrival, 48 hours after phototherapy, and 24 hours following phototherapy.

Method of measurement
Blood sample

2

Description
Calcium

Timepoint
The calcium level of each newborn were tested on arrival, 48 hours after phototherapy, and 24 hours following phototherapy.

Method of measurement
Blood sample

3

Description
Magnesium

Timepoint
The calcium level of each newborn were tested on arrival, 48 hours after phototherapy, and 24 hours following phototherapy.

Method of measurement
Blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Case group intervention: The occipital area of this group during phototherapy was covered by a hat. Calcium and magnesium levels were checked at the beginning, 48 hours after starting phototherapy, and 24 hours after the treatment. All the infants were placed under phototherapy with 8 Lamp, 40 watts, blue light with a wavelength of 470-410 nanometers, at a distance of 40 -30 cm from the body surface area. Calcium level equal to or less than 7.5 mg/dl was considered as hypocalcaemia and Mg level equal to or less than 1.2 mg/dl was considered as hypomagnesaemia. White cabling Hat was used for newborns.

Category

Prevention

2

Description
Control group intervention: Routine phototherapy was used for first group. Calcium and magnesium levels were checked at the beginning, 48 hours after starting phototherapy, and 24 hours after the treatment. All the infants were placed under phototherapy with 8 Lamp, 40 watts, blue light with a wavelength of 470-410 nanometers, at a distance of 40-30 cm from the body surface area.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Moslemin Hospital
Full name of responsible person
Shahla Yousefi
Street address
Khayam street, Zand BLVD, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reasearch , Shiraz University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Vice chancellor for reasearch office, Shiraz University of Medical Sciences building, Zand BLVD
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reasearch , Shiraz 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
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Position
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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