

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 hyperbilirubinemia 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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Zahra Jamshidi

Name of organization / entity

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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 serum 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 between 13 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

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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

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Kargar

Position

Msc of Pediatric Nursing

Other areas of specialty/work

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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