

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of head covering in prevention of phototherapy induced hypocalcaemia in icterus newborns with gestational age Less than 35 weeks

Protocol summary

Summary

Objective Such complications of phototherapy include seizure, apnea and lethargy is noxious. This study designed to evaluate of head and head covering during phototherapy in prevention of this complications Design This study is a prospective randomized clinical trial which was conducted on premature infants with gestational age less than 35 weeks since March 2014 to March 2015. In this study 86 preterm infants divided into two groups (n = 43) Setting and conduct In both intervention and control group underwent phototherapy using 4 fluorescent lamps in the blue color in distance of 35 cm. Eyes and genitalia were protected. Over the head and head was covered using cloth helmet with a suitable size only in intervention group. Total serum calcium was measured before and 36 hours after Phototherapy in both group. Total calcium below 8 mg/dL was considered as hypocalcemia in both groups Inclusion and Exclusion criteria Inclusion criteria: preterm infants with gestational age less than 35 weeks with Jaundice who needed phototherapy; lack of congenital malformations at birth; the infant's mother did not suffer from gestational diabetes or hyperparathyroidism; the infant's mother did not take anticonvulsive drugs during pregnancy; lack of prenatal asphyxia (Apgar score 5 minutes, 0 to 3 and bicarbonate ph birth less than 7 and umbilical cord less than 12); the infant was not treated with sodium bicarbonate; the baby with no exchange transfusion, IUGR and sepsis. Exclusion criteria: Affection of neonatal sepsis; administration of sodium bicarbonate; exchange transfusion Intervention Head covering during phototherapy Main outcome measures Calcium measurement

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042321910N1**

Registration date: **2015-12-30, 1394/10/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Behzad Barekatin

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of head covering in prevention of phototherapy induced hypocalcaemia in icterus newborns with gestational age Less than 35 weeks

Public title

The effect of head covering in prevention of Phototherapy induced hypocalcaemia in icterus newborns with gestational age Less than 35 weeks

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: preterm infants with gestational age less than 35 weeks with Jaundice who needed phototherapy; lack of congenital malformations at birth; the infant's mother did not suffer from gestational diabetes or hyperparathyroidism; the infant's mother did not take anticonvulsive drugs during pregnancy; lack of prenatal asphyxia (Apgar score 5 minutes, 0 to 3 and bicarbonate ph birth less than 7 and umbilical cord less than 12); the infant was not treated with sodium bicarbonate; the baby with no exchange transfusion , IUGR and sepsis. Exclusion criteria: Affection of neonatal sepsis, administration of sodium bicarbonate, exchange transfusion

Age

To **1 month** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

Hezarjerib bolvar, Isfahan University of Medical Science

City

Isfahan

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

393915

Health conditions studied

1

Description of health condition studied

Neonatal Jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

2

Description of health condition studied

Neonatal hypocalcemia

ICD-10 code

P71.1

ICD-10 code description

Other neonatal hypocalcaemia

Primary outcomes

1

Description

serum calcium

Timepoint

before and 36 hourse after phototherapy

Method of measurement

Measurement of serum calcium

Secondary outcomes

1

Description

Jitteriness

Timepoint

During study

Method of measurement

Observation and Physical examination

2

Description

Siezure
Timepoint
During study
Method of measurement
Observation and Physical examination

3

Description
Apnea
Timepoint
During study
Method of measurement
Observation and Physical examination

Intervention groups

1

Description
Intervention group: Head covering during phototherapy for prevention of hypocalcemia
Category
Prevention

2

Description
Control group: Phototherapy without head covering
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
shahid beheshti hospitals
Full name of responsible person
Behzad Barekatin
Street address
Isfahan, Felezi Bridge
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Isfahan University of Medical Science
Full name of responsible person
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Hezarjerib bolvar, Isfahan University of Medical Science
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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 research of Isfahan University of Medical Science
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

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Behzad Barekain

Position

Academic member of Isfahan University of Medical Sciences, Neonatologist

Other areas of specialty/work**Street address**

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City

Isfahan

Postal code**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