

# 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)

##### Phone

+98 31 3261 6670

##### Email address

b\_barekatin@med.mui.ac.ir

#### 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  
**City**  
Isfahan

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Vice Chancellor for research of Isfahan University of Medical Science  
**Full name of responsible person**  
Mehdi Nematbakhsh  
**Street address**  
Hezarjerib bolvar, Isfahan University of Medical Science  
**City**  
Isfahan  
**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

**Contact**  
**Name of organization / entity**  
Isfahan University of Medical Science  
**Full name of responsible person**  
Neda Hosseini  
**Position**  
Resident of Pediatrics  
**Other areas of specialty/work**  
**Street address**  
Department of pediatrics, Isfahan University of Medical Science  
**City**  
Isfahan  
**Postal code**  
**Phone**  
+98 31 3386 8247  
**Fax**  
**Email**  
neda.8892@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Behzad Barekatin  
**Position**  
Academic member of Isfahan University of Medical Sciences, Neonatologist  
**Other areas of specialty/work**  
**Street address**  
Nom 302, Arian apartment building, Mehran ave, Moshtagh st, Isfahan  
**City**  
Isfahan  
**Postal code**

**Phone**

+98 31 3261 6670

**Fax****Email**

b\_barekatin@med.mui.ac.ir

**Web page address****Phone**

+98 31 3261 6670

**Fax****Email**

b\_barekatin@med.mui.ac.ir

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

Isfahan University of Medical Sciences

**Full name of responsible person**

Behzad Barekatin

**Position**

Academic member of Isfahan University of Medical Sciences, Neonatologist

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

Nom 302, Arian apartment building, Mehran ave,  
Moshtagh st, Isfahan

**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*