Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of head coverage on the prevention of hypocalcemia and hypo magnesium caused by photo-therapy in premature infants with jaundice.

Protocol summary

Study aim

Evaluation of the effect of head coverage on the prevention of hypocalcemia and hypomagnesemia caused by photo-therapy in premature infants with jaundice.

Design

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct

The aim of this study was to investigate the effect of head covering on prevention of hypocalcemia and hypomagnesemia resulting from phototherapy on jaundice infants admitted to the Shahidan Mobini Hospital in Sabzevar. In this study, participants were unaware of how infants were grouped. infants are randomly assigned to the intervention group (cover the head with a hat) and the control (without hat). The response to treatment will be evaluated by checking before and 48 hours after phototherapy the total serum calcium, magnesium, and bilirubin levels in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 30-35 weeks; Perinatal asphyxia; lack of congenital anomaly; lack of neonatal sepsis and IUR; lack of receiving sodium bicarbonate and exchange of blood; non-interference head covering during phototherapy; lack of mother's catch to gestational diabetes and hyperparathyroidism. Exclusion criteria: Neonatal sepsis, Perinatal asphyxia, Congenital anomalies, Receiving sodium bicarbonate and exchange blood, Mother's catch to gestational diabetes and hyperparathyroidism, IUR.

Intervention groups

Intervention group: In this group, the patient's head is covered with a hat, using a white cotton hat. Before and 48 hours after phototherapy, total serum calcium, magnesium, and bilirubin levels are measured. Control group: In this group, no specific work is done for patients, and total serum calcium, magnesium, and bilirubin levels are measured before and 48 hours after phototherapy.

Main outcome variables

Determination of the mean serum level of calcium and magnesium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N1**
Registration date: **2018-10-26, 1397/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-26, 1397/08/04**
Update count: **0**

Registration date

2018-10-26, 1397/08/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-15, 1397/07/23

Expected recruitment end date

2019-01-13, 1397/10/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of head coverage on the prevention of hypocalcemia and hypo magnesium caused by photo-therapy in premature infants with jaundice.

Public title

The effect of head coverage on the prevention of hypocalcemia and hypomagnesia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 30-35 weeks Lack of congenital anomaly since birth Lack of receiving sodium bicarbonate and exchange of blood Lack of mother's catch to the gestational diabetes and hyperparathyroidism Lack of using anticonvulsants by mother during pregnancy Non-interference head covering during phototherapy Perinatal asphyxia (Apgar score in the minute 5 between 0 to 3, Ph and bicarbonate of the umbilical cord less than 7 and 12 respectively).

Exclusion criteria:

Neonatal sepsis Perinatal asphyxia Congenital anomalies since birth Receiving sodium bicarbonate and exchange blood Mother's catch to the gestational diabetes and hyperparathyroidism Mother's use of anticonvulsants during pregnancy Intrauterine gestational retardation Interventions cover the head during phototherapy

Age

From **8 months** old to **9 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization based on permutation. Accordingly, 30 blocks were allocated to patients, in each block 2 from A treatment group and 2 from the B treatment group were placed. Eventually, after completion of the blocks, Group A is covered with a hat and group B does not get any special action.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person in the study will be assigned code A and B, that the researcher will only be known of the type of groups. The outcome evaluator and the practitioner is unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2018-09-18, 1397/06/27

Ethics committee reference number

IR.MEDSAB.REC.1396.035

Health conditions studied

1

Description of health condition studied

Jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Hypocalcemia: A deficiency and low serum calcium concentration in the blood, usually less than 1.2 mmol / L or 9 mg / dL.

Timepoint

At the beginning of the study (before the intervention) and 48 hours after phototherapy

Method of measurement

Flame photometry device

2

Description
Hypo-magnesium: A deficiency and low serum concentration of magnesium in the blood, which is usually less than 1.5 mg per cent.
Timepoint
At the beginning of the study (before the intervention) and 48 hours after phototherapy
Method of measurement
Flame photometry device

Secondary outcomes

1

Description
Neonatal Jaundice or Hyperbilirubinemia (i.e., over 2 mg / dL)
Timepoint
At the beginning of the study (before the intervention) and 48 hours after phototherapy
Method of measurement
Flame photometry device

Intervention groups

1

Description
Intervention group: In this group, the patient's head is covered with a hat, using a white cotton hat. Before and 48 hours after photo therapy, total serum calcium, magnesium, and bilirubin levels are measured.
Category
Treatment - Devices

2

Description
Control group: In this group, no specific work is done for patients, and total serum calcium, magnesium, and bilirubin levels are measured before and 48 hours after photo therapy.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmatiyeh hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Sabzevar University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
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Position
Assistant Professor
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available