

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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

Name

Mohammad Sahebkar

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

Samaneh

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Heshamatiyeh Hospital, Asadabady Ave., Sabzevar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

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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

Full name of responsible person

Dr. Nasrin Hashemian

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Practitioner

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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