

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of phototherapy on serum 25(OH) vitamin D level in neonatal hyperbilirubinemia

Protocol summary

Study aim

The effect of phototherapy on serum 25 hydroxyvitamin D levels in neonatal hyperbilirubinemia

Design

All the newborns with an age of more than 72 hours that had been referred to Amirkola Children's Hospital (ACH) with serum bilirubin level more than 15mg/dl have been considered as the case group and received phototherapy according to the ACH phototherapy protocol. Bilirubin was checked by spectrophotometry method by chemical kits and serum 25(OH) vitamin D level was checked by ELISA; in two times before phototherapy and 72 hours after the start of phototherapy. The primary consequences: Determination of serum 25(OH) vitamin D levels. The secondary consequence: Determination of serum bilirubin level that would be compared before and after the intervention.

Settings and conduct

All the newborns with an age of more than 72 hours that had been referred to Amirkola Children's Hospital (ACH)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Term infants (weight: 2500–4000 g) who required phototherapy, Infant From 3 day old to 28 days old Exclusion Criteria: Infants with congenital anomalies Asphyxia prenatal (birth, APGAR score less than 4 at 1 minute or less than 7 at 5 minutes of birth, Incidence of clinical signs of sepsis or blood cultures during phototherapy, the need for blood transfusions during the study, Incidence clinical benefit of Kernicterus

Intervention groups

Get a phototherapy at a distance of 20 centimeters from the body surface

Main outcome variables

serum 25 hydroxyvitamin D levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180925041133N1**

Registration date: **2018-10-08, 1397/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-08, 1397/07/16**

Update count: **0**

Registration date

2018-10-08, 1397/07/16

Registrant information

Name

Yadollah Zahedpasha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 2151

Email address

y.zahedpasha@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of phototherapy on serum 25(OH) vitamin D level in neonatal hyperbilirubinemia

Public title

The effect of phototherapy on serum vitamin D level in neonatal hyperbilirubinemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Term infants (weight: 2500–4000 g) who required phototherapy From 3 day old to 28 days old

Exclusion criteria:

Infants with congenital anomalies Asphyxia prenatal (birth, APGAR score less than 4 at 1 minute or less than 7 at 5 minutes of birth Incidence of clinical signs of sepsis or blood cultures during phototherapy The need for blood transfusions during the study Incidence clinical benefit of Kern icterus

Age

From **3 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

45745-47176

Approval date

2018-09-18, 1397/06/27

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.134

Health conditions studied

1

Description of health condition studied

Neonatal Hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

25(OH) vitamin D

Timepoint

Before phototherapy and 72 hours after the start of phototherapy

Method of measurement

ELISA - ng/ml

Secondary outcomes

1

Description

Bilirubine level

Timepoint

at admission, phototherapy, discharge time

Method of measurement

Measuring of the total serum bilirubin level by biochemistry kits manufactured in Iran and by the method of spectrophotometry.

Intervention groups

1

Description

Infants received phototherapy at a distance of 20 centimeters from the body surface. Bilirubin was checked by spectrophotometry method by chemical kits and serum 25(OH) vitamin D level was checked by ELISA; in two times before phototherapy and 72 hours after the start of phototherapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Children's Hospital

Full name of responsible person

Yadollah Zahedpasha

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No 19, Amirkola Children's Hospital, Amirkola, Babol,

Mazandaran Province, IR Iran.

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Yadollah Zahedpasha

Position

Full professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Mousa Ahmadpour-Kacho

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Yadollah Zahedpasha

Position

Full professor

Latest degree

Subspecialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available