Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy and complication the distance phototherapy lamps of the surface body infant with jaundice

Protocol summary

Study aim

determine the effects and complication of phototherapy on reducing of serum bilirubin in neonates with jaundice.

Design

This study was approved by the Ethics Committee of Sabzevar University of Medical Sciences, with IR.MEDSAB.REC.1396.1 code number of ethics. purposely consent obtained from each patient's guardian. Research environment was neonatal intensive care unit of Imam Reza Hospital.

Settings and conduct

In a randomized clinical trail 60 term and near to term newborns with jaundice that ages were older than 24hours andweight >2000, who were admitted to the neonatal intensive care unit of mashhad Imam Reza Hospital. newborn had entry criteria were parallel assigned two groups of control and intervention after being satisfied with their parents.Initiation of phototherapy the infant were treated naked except for diapers and eye pads and weighed daily. Neonate position during this study was supine. The complications of phototherapy such as hypertermia,skin rash,diarrhea were evaluated every 6 hours and recorded in the daily information form.The serum bilirubin was measured at begining of the study, 12 hours and 24 hours after phototherapy. Also, for the duration of phototherapy, the serum bilirubin was measured every 24 hours from second day. To measureing the serum bilirubin levels, blood samples were taken from the back of the arm (1 cc) and sent to Imam Reza Hospital lab. Blood samples were not be shaken for avoiding hemolysis. .

Participants/Inclusion and exclusion criteria

term and near to term newborns with jaundice that ages were older than 24hours andweight >2000, who were admitted to the neonatal intensive care unit of mashhad Imam Reza Hospital.

Intervention groups

The control group was treated with phototherapy at a distance of 45 cm from the body surface of the newborn and the intervention group was treated with phototherapy at a distance of 20 cm from the body surface of the newborn's body.

Main outcome variables

The distance of phototherapy lamps from the body surface will be effective in reducing the serum bilirubin levels in the jaundiced neonates and will not increase the complication phototherapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170922036321N1**
Registration date: **2017-12-02, 1396/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-02, 1396/09/11**
Update count: **0**

Registration date

2017-12-02, 1396/09/11

Registrant information

Name

Fatemeh Parvin

Name of organization / entity

Sabzevar University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date
2017-05-05, 1396/02/15
Expected recruitment end date
2018-01-04, 1396/10/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and complication the distance phototherapy lamps of the surface body infant with jaundice

Public title
The effect of reducing light bulb distance in reducing jaundice in newborns with jaundic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Term neonate(gestational age >32 weeks) with weight more than 2000 grams; No congenital anomalies؛ No congenital infections; Normal suking reflux;neonate after 24 hours had diuresis and defication; Bilirubin serum in the second day (10-15 mg/dl), third day (13-17 mg/dl), fourth day (14-15 mg/dl),fifth to seventh days (15-18 mg/dl) seventh days and more (18-20 mg/dl)l; there is no indication of Rh incompatibility. weight more than 2000 grams No congenital anomalies؛ No congenital infections Normal suking reflux neonate after 24 hours had diuresis and defication neonate age older than 24 hours Bilirubin serum in the second day (10-15 mg/dl), third day (13-17 mg/dl), fourth day (14-15 mg/dl),fifth to seventh days (15-18 mg/dl) seventh days and more (18-20 mg/dl) there is no indication of Rh incompatibility
Exclusion criteria:
Parental withdrawal from continuing research with infants infected during the study Patient's need for blood transfusion Patient's need for IVIG jaundice due to the following causes; G6PD deficiency and hypothyroidism; and Rh and ABO incompatibility; and evidence of hemolysis
Age
From **2 days** old to **21 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
newborn had entry criteria were parallel assigned two groups of control and intervention after being satisfied with their parents
Blinding (investigator's opinion)
Single blinded
Blinding description
The experimenter did not know which sample is in the intervention group and which sample is in the control group?
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Sabzevar University of Medical Sciences
Street address
Campus Complex of Sabzevar Medical University,Tohidl levard, Sabzevar.
City
Sabzeva
Province
Razavi Khorasan
Postal code
00989157918889
Approval date
2017-05-01, 1396/02/11
Ethics committee reference number
IR.MEDSAB.REC.1396.1

Health conditions studied

1

Description of health condition studied
Jaundice
ICD-10 code
p59
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Neonatal blood serum Bilirubin
Timepoint
At the reception, 12 hours and 24 hours after the start of phototherapy
Method of measurement
Neonatal venous blood sampling

Secondary outcomes

1

Description
Baby body temperature
Timepoint
Every 6 hours
Method of measurement
thermometer

2

Description
Skin rash
Timepoint
Every 8 hours
Method of measurement
Abservation

3

Description
Weight Loss
Timepoint
Daily
Method of measurement
Daily weighing

4

Description
Incidence of loose stools
Timepoint
Every 8 hours
Method of measurement
Abservation

Intervention groups

1

Description
The control group was treated with phototherapy at a distance of 45 cm from the body surface of the newborn's body.
Category
Treatment - Other

2

Description
Intervention group: This group was treated with phototherapy at a distance of 20 cm from the body surface of the newborn's body
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Nicu Imam Reza Hospital (AS)
Full name of responsible person
Fatemeh Parvin
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Sabzevar University of Medical Sciences
Full name of responsible person
Mrs. Zardast
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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, 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
Mrs Roghayeh Zardosht
Full name of responsible person
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Position
PHD. In Nursing
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available