Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Kangaroo Mother Care (KMC) on serum bilirubin level in full term newborns with hyperbilirubinemia admitted for phototherapy

Protocol summary

Summary

The aim of this study is to determine the effect of Kangaroo Mother Care on serum bilirubin levels in full term newborns with hyperbilirubinemia admitted for photo-therapy. This study is a clinical trial which 106 infants select randomly in the intervention and control groups with inclusion criteria: (2500 to 4000 grams birth weight ...) and exclusion criteria: (Baby's hyperbilirubinemia results from breastfeeding ...). Standard method is used to photo-therapy, involving the use of a 4 lamps photo-therapy with blue lights for each incubator, range light is 420 to 480 nano-meters and the distance from the baby is 35 to 40 centimeters. In the experimental group, a baby who is under photo-therapy, get intermittently out of the photo-therapy and is handed over to the mother. The mother, who is wearing kangaroo care dress, puts the naked baby between her breasts, wearing only a diaper. The mother feeds the baby with her milk during hospitalization at least 6 times in the morning, evening and night shifts. Babies in the control group don't receive kangaroo care during the photo-therapy. Primary Outcome: Infants serum bilirubin levels (Before the intervention, 24, 48 and 72 hours after photo-therapy) Secondary outcomes: The infants' photo-therapy (Beginning and end of photo-therapy) and length of stay in hospital (From the time of admission until discharge from the neonatal unit).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505231760N40**
Registration date: **2015-05-30, 1394/03/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-30, 1394/03/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2015-01-07, 1393/10/17

Expected recruitment end date

2015-04-09, 1394/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Kangaroo Mother Care (KMC) on serum bilirubin level in full term newborns with hyperbilirubinemia admitted for phototherapy

Public title

The effect of Kangaroo Mother Care (KMC) on serum bilirubin level in full term newborns with

hyperbilirubinemia admitted for phototherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Birth weight is 2500 - 4000 grams; Gestational age at birth is 37 - 42 weeks; Apgar score is more than 7 from the first to fifth minutes; All newborns are hospitalized by recognizing the jaundice (from the end of second day to seventh day, diagnosed by a pediatrician); All infants are breastfed; No baby receives medication to reduce bilirubin; No exchange transfusion is performed on neonates; Both parents are Iranian; No baby is dehydrated; Neonate's age is more than 48 hours; Bilirubin level is 15 to 20 mg/dl. Exclusion criteria: Neonates suffer from congenital anomaly, respiratory failure and known infection; Infants have jaundice on the first day of birth; Baby’s hyperbilirubinemia results from breastfeeding; There are some signs of sepsis in neonates; Newborn suffers from cephalohematoma, purpura and petechia; There is a history of anemia or hyperbilirubinemia for his/her mother, father, sister or brother; Apgar score from first to fifth minute is less than 7; Neonate has umbilical artery catheter or chest tube; There is Rh incompatibility between mother and infant; Hyperbilirubinemia is owing to G6PD deficiency; Infant needs the exchange transfusion; Mother is not willing to cooperate during the study; Baby has intraventricular hemorrhage; Mother suffers from HBSAg+; Neonate is suspected to have TORCH.

Age

From **3 days** old to **7 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The intervention and control groups in terms of the characteristics of age, bilirubin and integration are ABO incompatibility.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical Sciences, Ganjafroz Avenu

City

Babol

Postal code

Approval date

2015-01-06, 1393/10/16

Ethics committee reference number

5032

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Neonatal serum bilirubin level

Timepoint

Before intervention, 24, 48 and 72 hours after intervention

Method of measurement

Laboratory

Secondary outcomes

1

Description

Duration of hospitalization in neonatal unit

Timepoint

Discharge time from neonatal unit

Method of measurement

Clinical

2

Description

Duration of Phototherapy

Timepoint

At the beginning and the end of phototherapy

Method of measurement

Clinical

Intervention groups

1

Description
Intervention groups: Using kangaroo mother care and photo-therapy. (KMC is clothing made of cotton. Open from behind and from the front of the pocket is great for putting baby in the hospital haute couture Amirkola be sewn.) (The four lamp with a blue light photo-therapy device for each Incubator, with a range of 420 to 480 NM light at a distance of 35 to 40 cm of the baby.
Category
Treatment - Other

2

Description
Control groups: Using only photo-therapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Hospital of Pediatrics
Full name of responsible person
Nasrin Rasuli Larma'i
Street address
Amirkola, Pediatrics Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Babol University of Medical Sciences
Full name of responsible person
Dr. Ali Bijani
Street address
Babol University of Medical Sciences, Ganjafroz Avenue
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Babol
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 and Technology, Babol University of Medical Sciences
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Babol University of Medical Sciences
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Nargess Gholizadeh Pasha
Position
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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