

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison the effect of kangaroo mother care (KMC) with Field massage on serum bilirubin level in full term newborns with hyperbilirubinemia admitted for phototherapy

Protocol summary

Study aim

Determine the effect of kangaroo mother care (KMC) with Field massage on serum bilirubin level in full term newborns with hyperbilirubinemia admitted for phototherapy

Design

A clinical trial with a control group and two intervention groups (massage and kangaroo mother care), With parallel groups from available samples without blindness, Randomized using random numbers table, Sample size 90 people, 30 people in the control group, 30 people in the massage group and 30 people in the kangaroo care group.

Settings and conduct

90 term neonates with hyperbilirubinemia admitted in Imam Khomeini and Aiatollah Rohani hospital will be selected and randomly divided into two intervention and one control groups. Conventional phototherapy was performed following the same procedure for all the neonates.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 37-42 weeks, Birth weight 2500-4000 g, No therapeutic treatment drugs for hyperbilirubinemia, Age over 48h of birth, Bilirubin 15-20 mg/dl. Exclusion criteria: ABO and Rh incompatibility, Positive Coombs, hemolysis, Bile duct and digestive tract obstruction, lack of glucose-6-phosphate dehydrogenase, Doubtful newborn to TORCH syndrome.

Intervention groups

Intervention group 1: kangaroo mother care (KMC): Along with phototherapy, KMC will be applied during breastfeeding at least five times over 24 h, for 3 consecutive days. Intervention group 2: Field massage: Along with phototherapy, receive a 15-minute massage three times a day (morning, noon and evening), for 3 consecutive days. Control group: The control group receives the routine care (phototherapy).

Main outcome variables

Evaluation of blood bilirubin reduction in patients in control and intervention groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039709N1**

Registration date: **2018-08-06, 1397/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-06, 1397/05/15**

Update count: **0**

Registration date

2018-08-06, 1397/05/15

Registrant information

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Razie Lori Kenari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision the effect of kangaroo mother care (KMC) with Field massage on serum bilirubin level in full term newborns with hyperbilirubinemia admitted for phototherapy

Public title

Comparision the effect of kangaroo mother care (KMC) with Field massage on serum bilirubin level in full term newborns with hyperbilirubinemia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age 37-42 weeks Birth weight 2500-4000 g Apgar score from first to fifth minutes above 7 Receiving phototherapy for hyperbilirubinemia Breast feeding No drug to reduce bilirubin Age older 48 hours after birth Bilirubin 15-20 mgr/dl

Exclusion criteria:

ABO and Rh incompatibility, Possitivecoombs, hemolysis subgaleal hemorrhage, cephal hematoma, purpura Congenital anomaly infection Bile duct and digestive tract obstruction lack of glucose-6-phosphate dehydrogenase, Doubtful newborn to TORCH syndrom

AgeFrom **2 days** old to **28 days** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

In this clinical trial, 90 term neonates with hyperbilirubinemia will be select and randomly divided into two intervention and one control groups. Randomization starts from a random point from a random number table and For a number of interventions, the intervention group and the control group are used a random permutation method, So that random numbers 0-4 for random permutation A B {(control B) (intervention A)} and Random numbers 5-9 are used for the random permutation B A {(Intervention A) (Control B)}.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

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Postal code

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Approval date

2018-04-28, 1397/02/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.011

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 blood bilirubin level

Timepoint

Measurement of Bilirubin level at 24, 48, and 72 h after phototherapy and Intervention

Method of measurement

Measurement of serum bilirubin levels in neonatal blood samples

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: kangaroo mother care (KMC):In the intervention group, in addition to standard phototherapy, KMC Will be apply by the mother. The mother after

wearing a special gown laid on a folding bed, while the naked infant (wearing only a diaper and a hat) will be place between her breasts by a nurse. During hospitalization, KMC will be apply for 30-45 min at least five times a day in the morning, afternoon, and night.

Category

Treatment - Other

2

Description

Intervention group: Field massage : Massage Will be done with the soft parts of the fingers of both hands with light pressure by the researcher using field technique. Massage duration was 15 minutes, and include three steps each lasting five minutes, according to the same study. During the first and final stages, the infant is placed in prone position, and each minute one of the following areas is massage: A) 12 massage moves (every five seconds one move) from head downwards (both sides of the face to neck and reversely); B) 12 massage motions from the neck to the shoulders and reversely; C) 12 massage moves from the upper back down to the waist and reversely; D) 12 massage moves from the thighs down to the ankles and reversely; E) 12 massage motions from the shoulders to the wrists and reversely, in the middle phase, the infant was put in supine position and six extension and flexion moves were done (10 seconds for each) in the right arm, left arm, right leg, left leg, and both legs.

Category

Treatment - Other

3

Description

Control group: the newborns in the control group (age and weight similar to the intervention groups)is recived standarde phototherapy and only breastfeed by the mother, whereas KMC and massage do not apply.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khomeini 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

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

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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