Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of bilirubin levels on preterm infants 30-36 weeks gestational age in massage and routine care groups

Protocol summary

Summary

The incidence of Hyperbilirubinemia as a physiological problem in nearly 80% of preterm infants occur during the first week of birth, and massage therapy is one of the most common CAM therapies in the world. This study aimed to examine the effects of massage on serum Bilirubin levels in preterm infants and the aforementioned population were all the preterm infants with a gestational age between 30 and 36 weeks of hospitalization with consider to the characteristics of participants of the study (Apgar score above 7, weighing more than 1250 g and stabilization of patient's condition) in the neonatal intensive care unit of Ghaem, Imam Reza and Omm-Albanin hospitals in Mashhad city. Billy test device, the demographic information and daily record questionnaires were data collection tools. In this clinical trial, 80 infants were selected by simple non-probability sampling and allocated into intervention and control groups. In the intervention group, massage was performed 2 times a day for 5 consecutive days with Field technique by researcher which the total time of massage was 15 minutes consisted of three 5-minutes phases; the routine care was carried out in the control one. Defecation frequency and the skin Bilirubin levels were measured and recorded before intervention and after that daily until tenth day after birth or discharge day in both groups. The neonates were excluded if they would catch neonatal clinical jundice or Icter treatment after 24 hours after birth, any proof of known causes of jaundice and suffering from infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206059949N1**
Registration date: **2015-06-22, 1394/04/01**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-06-22, 1394/04/01

Registrant information

Name
Maryam Lotfi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2012-10-28, 1391/08/07

Expected recruitment end date

2013-03-10, 1391/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of bilirubin levels on preterm infants 30-36 weeks gestational age in massage and routine care groups

Public title

Effects of massage on bilirubin levels in preterm infants

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: stabilization of neonate's condition (12-24 hours after birth), Apgar score 7 or more, gestational age 30-36 weeks, weighing more than 1250 g, 5th minutes after birth Apgar score 7 or more, lack of any massage contraindication (like wound, skin lesions, burn, ecchymosis, fracture or joint dislocation, infectious rush and hyperthermia), lack of obvious congenital anomalies, absence of congenital infection Exclusion criteria: getting neonatal clinical Icter after 24 hours after birth, any proof of known causes of jaundice like: Glucose-6-phosphate dehydrogenase deficiency, hypothyroidism, RH or ABO incompatibility or any evidence of erythrocytes lysis, getting phototherapy, blood transfusion and medication (drugs such as intravenous Immunoglobulin, Metalloporphyrins and Clofibrate) for jaundice a day after birth, Infection during the study (blood culture or cerebrospinal fluid culture - positive CSF).

Age
From **7 months** old to **8 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Mashhad University of Medical Sciences

Street address
After Doktora Cross, Daneshgah Avenue, Taghi Abad Square

City
Mashhad

Postal code
345-91375

Approval date
2012-10-20, 1391/07/29

Ethics committee reference number
910140

Health conditions studied

1

Description of health condition studied
Neonatal jaundice, unspecified

ICD-10 code
P59.9

ICD-10 code description
Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description
skin bilirubin levels

Timepoint
Before the intervention, and then daily until the tenth day or discharged date

Method of measurement
in mg/dl with transcutaneous bilirubinometry

Secondary outcomes

1

Description
stool frequency

Timepoint
daily until the tenth day or discharged date

Method of measurement
Depending on the number recorded in the infants’ files

Intervention groups

1

Description
Intervention group : In the intervention group, the researcher will be massaged the infants twice a day on five consecutive days. Before the intervention, transcutaneous bilirubin levels are determined using a bilirubin analyzer. The researcher washes her hands thoroughly and warms and oils them, and will be massaged the infants with the soft parts of the fingers of both hands applying gentle pressure and using Field’s technique. The neonates massage will carry out in 15-minute sessions. Each session consisted of 3 standardized phases of 5 minutes each, in which the infants were keep in a prone position in the 1st and 3rd phase. The tactile stimulation procedure included 12 strokes at a rate of approximately 5 seconds per stroking motion over each region of the neonate in the following sequence: From the top of the head down the sides of the face to the neck, and vice versa; From the back of the neck to both ends of the shoulders, and vice versa; From the thighs down to the ankles, and vice versa; From

the shoulders down the arms to the wrist, and vice versa. In the middle phase, the neonate will make to lie in a supine position for kinesthetic stimulation that included 5 segments of 1 minute each which consist of 6 passive flexion/extension movements, each lasting 10sec. The stimulation will do on each arm, then each leg and lastly both legs together.

Category

Other

2

Description

The control group: Infants in the control group will receive routine care and no intervention will be performed on them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Maryam Lotfi

Street address

Ghaem Hospital, Ahmad Abad Boulevard, Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Maryam Lotfi

Street address

Imam Reza Square, Ebn-e Sina Avenue, Mashhad

City

Mashhad

3

Recruitment center

Name of recruitment center

Omm_Albanin Hospital

Full name of responsible person

Maryam Lotfi

Street address

Corner of Behjat 16, Ayatollah Behjat Avenue, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

After Doktora Cross, Daneshgah Avenue, Taghi Abad Square

City

Mashhad

Grant name

گرانت پژوهشی سال 1391 خانم سهیلا کربندی

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research deputy of Mashhad 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

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Soheila Karbandi

Position

Master

Other areas of specialty/work

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Neonatal specialist, associate professor

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Student of Master degree in Neonatal Intensive Care Nursing

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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