

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Massage on Serum Bilirubin Levels in Preterm Neonates affected with Hyperbilirubinemia

Protocol summary

Summary

Aim: To determine the effect of massage on serum bilirubin levels in preterm neonates affected with hyperbilirubinemia. Infants admitted to Hashemi-Nejad hospital who have inclusion criteria, will be divided into two categories based on gestational age: 32-34 and 35-37 weeks. Then they will randomly be assigned to control and massage groups. Neonates of control group will receive routine ward care and neonates of treatment group will receive massage intervention. The intervention consists of massage 20 minutes, twice daily, for 4 days. Massage will be done one hour after the morning feeding and one hour after noon feeding. Massage starting on the face, mothers use two thumbs gently rubbing the preorbital and cheek regions; and then moving on the chest, two hands of performer from the lower margin of chest slide to opposite upper edge alternately; then to the abdomen, corresponding to the conformation of colon, the performer push a half circle gently, next is on the limbs, the performer use hand by hand with moderate pressure external side of the upper and lower limbs; and finally the back, the performer slide two hand from vertebra to two sides by neck to buttock.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111013150N2**

Registration date: **2012-08-21, 1391/05/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-21, 1391/05/31

Registrant information

Name

Mahdi Basiri Moghadam

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 53 3722 3028

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basiri1344@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gonabad university of medical sciences

Expected recruitment start date

2011-11-06, 1390/08/15

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Massage on Serum Bilirubin Levels in Preterm Neonates affected with Hyperbilirubinemia

Public title

The Effect of Massage on Serum Bilirubin Levels in Preterm Neonates affected with Hyperbilirubinemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Parental satisfaction to participate their child in the study; Absence of jaundice in the first day; gestational age < 37 weeks; being breastfed; Absence of infection and any disease during the study. Exclusion

criteria: the desire of the parents to be omitted from the study; diseases or infections occurring in the course of the study; Discharge before completing the treatment period; Treatment be started with phototherapy.

Age

To 5 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gonabad university of medical sciences

Street address

Vice chancellor for research, Gonabad university of medical sciences, Next to the Asian Road

City

Gonabad

Postal code

96915

Approval date

2011-07-23, 1390/05/01

Ethics committee reference number

90/4

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

bilirubin level

Timepoint

daily

Method of measurement

transcutaneous bilirubin test

Secondary outcomes

1

Description

Jaundice

Timepoint

End of the study

Method of measurement

Clinical Signs

Intervention groups

1

Description

Neonates of control group will receive routine ward care.

Category

N/A

2

Description

Neonates of treatment group will receive massage intervention. The intervention consists of massage 20 minutes, twice daily, for 4 days. Massage will be done one hour after the morning feeding and one hour after noon feeding. Massage starting on the face, mothers use two thumbs gently rubbing the preorbital and cheek regions; and then moving on the chest, two hands of performer from the lower margin of chest slide to opposite upper edge alternately; then to the abdomen, corresponding to the conformation of colon, the performer push a half circle gently, next is on the limbs, the performer use hand by hand with moderate pressure external side of the upper and lower limbs; and finally the back, the performer slide two hand from vertebra to two sides by neck to buttock.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashemi-Nejad Hospital

Full name of responsible person

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Ali Ekrami
Street address
Next to the Asian Road
City
Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
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Master of Science, in Nursing Education, Faculty
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Person responsible for updating data

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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