Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 53 3722 3028

Email address

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
Mahdi Basiri Moghadam
Position
Master of Science, in Nursing Education, Faculty Member
Other areas of specialty/work
Street address
Deputy for Research, Gonabad University of Medical Sciences, Next to the Asian Road
City
Gonabad
Postal code
96915
Phone
+98 53 3722 3028
Fax
Email
Basiri1344@gmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Mahdi Basiri Moqadam
Position
Master of Science in Nursing Education, Faculty Member
Other areas of specialty/work
Street address
Deputy for Research, Gonabad University of Medical Sciences, Next to the Asin Road
City
Gonabad
Postal code
96915
Phone
+98 53 3722 3028
Fax
Email
Basiri1344@gmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Mahdi Basiri Moqadam
Position
Master of Science in Nursing Education, Faculty Member
Other areas of specialty/work
Street address
Deputy for Research, Gonabad University of Medical Sciences, Next to the Asian Road
City
Gonabad
Postal code
96915
Phone
+98 53 3722 3028
Fax
Email
Basiri1344@gmu.ac.ir
Web page address

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