Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Massage on Serum Bilirubin Levels in Term Neonates ffected with Hyperbilirubinemia

Protocol summary

Summary

Aim: studying the effect of massage on serum bilirubin levels in term infants with hyperbilirubinemia. This clinical trial research will be carry out on full-term infants with hyperbilirubinemia at the "22 Bahman Hospital" in Gonabad, Iran. The infants hospitalized with hyperbilirubinemia will be randomly assigned into a massage group and a control group. The intervention consist of massage and passive movements carried out on the infants of the massage group in 15-minute, in 3 consecutive hours, daily for 4 days (inclusive of phototherapy treatment). The mean bilirubin levels were then monitored and compared with those of the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811043150N1**
Registration date: **2011-05-09, 1390/02/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-09, 1390/02/19

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

2009-05-31, 1388/03/10

Expected recruitment end date

2010-05-31, 1389/03/10

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 Term Neonates ffected with Hyperbilirubinemia

Public title

The Effect of Massage on Serum Bilirubin Levels in Term Neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: term neonates born after 37-42 weeks of pregnancy; weighing between 2500gm and 4000gm; having a bilirubin level of 13–24mg/dl; All the children were breast fed; were not under any medication and showed no contra-indications to massage. Exclusion criteria: having jaundice on the 1st day of birth; hyper bilirubinemia caused by hemolysis; diseases or infections occurring in the course of the study; blood transfusion carried out in the infant; the occurrence of bronze children's syndrome during phototherapy; diarrhea during phototherapy; and lastly the desire of the parents to be omitted from the study.

Age

From **2 years** old to **7 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

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 Gonabad univercity of medical sciences

Street address

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

City

Gonabad

Postal code

9691793718

Approval date

2010-04-21, 1389/02/01

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

Level of Serum Bilirubin

Timepoint

Daily

Method of measurement

Blood test

Secondary outcomes

1

Description

Jaundice

Timepoint

End study

Method of measurement

Clinical Sign

Intervention groups

1

Description

intervention groups: tactile and kinesthetic stimulation will carry out by the mother under the supervision of the researcher in 15-minute sessions in 3 consecutive hours, daily for 4 days. 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 neonates will gently stroke with the soft, smooth surfaces of all the fingers of both hands. 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. The neonate will then return to a prone position to repeat the tactile stimulation phase. Massage intervention will carry out alongside phototherapy (without interruption) in the sample group at a fix hour between 7am and 7pm every day. Initially, phototherapy lamps will check and adjust at a height of 30cm above the neonates who weill keep in the cots with eyes close and reproductory organs will protect. After every 2 hours of therapy a rest period of 30min. will give in which the neonates will allow to breast feed with eyes open. Bilirubin will measure at 6a.m. everydaycontrol group: without intervention.

Category

Treatment - Other

2

Description

control group will administer routine ward care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Gonabad University of Medical Sciences

Full name of responsible person
Mahdi Basiri Moqadam

Street address
Next to the Asian Road

City
Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, 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
Vice chancellor for research, 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 Moqadam

Position
Master of Science, in Nursing Education, Faculty Member

Other areas of specialty/work

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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