Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effects of Massage in Bilirubin in Term Neonatal with Hyperbilirubinemia in Care with Phototherapy Hospitalization in Neonatal Unit

Protocol summary

Summary

This study is an investigation of the influence of massage on bilirubin in neonates with hyperbilirubinemia. In this quasi-experimental and two groups study, 80 neonates with physiological neonatal jaundice hospitalization at Ali Ebn Abi Talib hospital in Zahedan, were selected with available and sequential sampling and divided randomly in two groups, intervention group (40) and control group (40). Neonates were term, birth weight was between 2000- 4000 gr and had physiological jaundice and exited from study if they had congenital disorders, respiratory failure and infection. The tools were demographic questionnaire and Transcutaneous-Billirubinometry. In the intervention group, Tactile- Kinesthetic massage was implemented for 2 days and 3 times every days and every session lasted 10 to 15 minutes. The mean of bilirubin have been determined in pre intervention, 24 hours and 48 hours after intervention. The subjects in control group received routine care and no intervention performed on them. During study, the researcher recorded all information relating to infant include, skin and serum level of bilirubin and number of feedings per day. Reducing the bilirubin level, had considered as primary outcome in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050411261N2**
Registration date: **2015-06-11, 1394/03/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-11, 1394/03/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2013-11-23, 1392/09/02

Expected recruitment end date

2015-01-03, 1393/10/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Massage in Bilirubin in Term Neonatal with Hyperbilirubinemia in Care with Phototherapy Hospitalization in Neonatal Unit

Public title

The Effects of Massage in Bilirubin in Neonates with Jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian; were normal birth weight and

term; breast feeding; having no Exchange Transfusion
Exclusion criteria: Having congenital disorders; respiratory failure; infection and cephalohematoma; needing to Exchange Transfusion and severe diarrhea

Age
From **2 days** old to **12 days** 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
Zahedan University of Medical Sciences and Health Services

Street address
Dr Hesaby Square, Janat Avenuse, Zahedan University of Medical Sciences, Zahedan

City
Zahedan

Postal code
0098

Approval date
2014-01-27, 1392/11/07

Ethics committee reference number
6025

Health conditions studied

1

Description of health condition studied
Neonatal physiological jaundice

ICD-10 code
P59.9

ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Indirect bilirubin

Timepoint
Pre intervention, 24 and 48 hours after intervention

Method of measurement
Transcutaneous-Billirubinometry

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, massage were implemented with tactile- kinesthetic massages. This method was implemented for 2 days and 3 times every days (9 AM, 3 PM and 7 PM) and every session lasted 10 to 15 minutes. The mean of bilirubin have been determined in pre intervention, 24 hours and 48 hours after latest massage (7 PM).

Category
Treatment - Other

2

Description
In control group, received routine cares and the mean of bilirubin have been determined in defined times.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Abne Abitaleb Hospital related to Zahedan University of Medical Sciences and Health Services

Full name of responsible person
Alieh Jalalodini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Zahedan University of Medical Sciences

Full name of responsible person
Dr. Hamidreza Mahmudzadeh Sagheb
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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
Vice Chancellor for Research and Technology, Zahedan 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

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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