

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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-Bilirubinometry. 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

Name

Alia Jalalodini

Name of organization / entity

Nursing and Midwifery College

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 2481

Email address

jalalodini@zaums.ac.ir

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-Bilirubinometry

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

Street address

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

City

Zahedan

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

Street address

Dr Hesaby Square, Janat Avenue, Zahedan
University of Medical Sciences, Zahedan

City

Zahedan

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**Contact****Name of organization / entity**

Nursing and Midwifery College, Zahedan University of
Medical Sciences

Full name of responsible person

Alia Alsadat Jalalodini

Position

Faculti member of science, Master of science in
nursing,

Other areas of specialty/work**Street address**

Mashahir Square, Nursing and Midwifery College,
Zahedan

City

Zahedan

Postal code

9816743463

Phone

+98 54 3341 9406

Fax**Email**

a_jalalodini@yahoo.com jalalodini@zaums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences,
Nursing and Midwifery College

Full name of responsible person

Manighe Nourian

Position

Faculti member of science, Master of science in
nursing, PhD student

Other areas of specialty/work**Street address**

Kodakyar Avenue, Evin Highway, Tehran

City

Tehran

Postal code

9985717443

Phone

+98 21 8820 2520

Fax**Email**

ma.nourian@uswr.ac.ir manighea@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Nursing and Midwifery College

Full name of responsible person

Alieh Jalalodini

Position

Faculti member of science, Master of science in
nursing

Other areas of specialty/work**Street address**

Mashahir Squire, Nursing and Midwifery College,
Zahedan

City

Zahedan

Postal code

9816743463

Phone

+98 54 3341 9406

Fax**Email**

a_jalalodini@yahoo.com jalalodini@zaums.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