

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A survey of Massage therapy effect on transcutaneous bilirubin in healthy term neonates

Protocol summary

Summary

The purpose of this study was to evaluate the effect of Massage therapy on transcutaneous bilirubin in healthy term neonates . The main inclusion criteria included gestational age more than 37, birth weight ≥ 2500 , breast feeding and postnatal age less than 12 h of life .The exclusion criteria were congenital anomaly, cephalhematoma .blood group incompatibility ,sepsis, formula feeding, exchange transfusion in previous sibling. Term newborns with postnatal age less than 12 h were included. The sample size included 100 uncomplicated neonates whom were randomly assigned into two different groups. massage group and control group. In both group transcutaneous bilirubin level measured from the first day to the fifth day postnatally . Normal care was given to the control group without massage. For massage group, specialized clinical staff gave 15-20 minutes of baby massage once daily from the first day to the fifth day postnatally ,according Miami protocol. The main outcome of this study was to see the effect of massage , on the level of transcutaneous bilirubin. The neonates were checked for the frequency of stool.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010274961N3**

Registration date: **2012-10-23, 1391/08/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-23, 1391/08/02

Registrant information

Name

Homa Babaei

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00988314276303 2292 داخلی

Email address

homa_babaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2013-02-03, 1391/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey of Massage therapy effect on transcutaneous bilirubin in healthy term neonates

Public title

A survey of Massage therapy effect on transcutaneous bilirubin in healthy term neonates

Purpose

Prevention

Inclusion/Exclusion criteria

The main inclusion criteria included gestational age more than 37, birth weight ≥ 2500 , breast feeding and postnatal age less than 12 h and those of the exclusion were congenital anomaly, cephalhematoma, blood group incompatibility ,sepsis, formula feeding, exchange

transfusion in previous sibling

Age
From **1 year** old to **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Kermanshah University of Medical Sciences

Street address
Building no=2, Sepah Avenue, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code
6714415333

Approval date
2012-03-18, 1390/12/28

Ethics committee reference number
7/420/62999پ

2

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

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City
kermanshah

Postal code
6714415333

Approval date
2012-03-18, 1390/12/28

Ethics committee reference number
7/420/62999پ

Health conditions studied

1

Description of health condition studied
neonatal hyperbilirubinemia

ICD-10 code
P59.9

ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
transcutaneous bilirubin

Timepoint
each 24 h

Method of measurement
by bilimeter

Secondary outcomes

1

Description
stool frequency

Timepoint
each 24

Method of measurement
inspection by mother

Intervention groups

1

Description
For massage group,(from the first day to the fifth day postnatal) clinical staff gave 15-20 minutes of baby massage once daily according university of Miami protocol

Category
Prevention

2

Description
newborns in the control group underwent routine daily care (without massage) and transcutaneous bilirubin level measured (from the first day to the fifth day postnatal) daily.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Reza Hospital, Kermanshah University of
Medical Sciences,

Full name of responsible person

Homa Babaei

Street address

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr farid Najafi

Street address

Deputy of Research, Kermanshah University of
Medical Sciences

City

kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei, MD

Position

Neonatologist

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

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Homa Babaei, MD

Position

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei

Position

Neonatologist

Other areas of specialty/work

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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