Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Massage on Response to Phototherapy in Newborns with Hyperbilirubinemia

Protocol summary

Summary

We have evaluated the effects of massage therapy on infants' response to phototherapy that were under treatment of hyperbilirubinemia. Enrolled infants were randomly divided into 2 groups: phototherapy alone (control/ no intervention group) and phototherapy + massage (case/ intervention group). The first baby referred was randomly determined to be enrolled in the control group, and the next infant was included in the case group. This process was repeated for each infant enrolled. Two phototherapy devices were randomly used in the case and control groups. Infants in the control group received traditional phototherapy and intensive care. Infants in the intervention group received massage in addition to conventional phototherapy and intensive care. Massage was performed thrice daily (every 8 h) for 30 min each. Before the massage, the hands of the researcher were warmed to the body temperature of the infant. Using gentle pressure, the researcher usually massaged different parts of the body with the soft parts of the fingers of both hands. Six organs of the body were massaged)lower limbs, upper limbs, abdomen, chest, back, and head and neck(.Patient data, including sex, birth weight, symptoms at presentation, duration of hospitalization, and treatment, were recorded by the pediatric resident or neonatal specialty doctor for each patient. A thorough examination of the newborn was done. Laboratory tests to determine the cause and severity of jaundice included to measure hematocrit, complete blood count, direct and indirect bilirubin, direct and indirect Coombs test, reticulocyte count, infant and maternal blood groups and Rh type).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108077244N1**

Registration date: **2016-05-16, 1395/02/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-16, 1395/02/27

Registrant information

Name

Hassan Boskabadi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 915 515 3987

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boskabadih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2013-02-21, 1391/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Massage on Response to Phototherapy in Newborns with Hyperbilirubinemia

Public title

Investigation of massage’s effect on phototropic answer in newborne jandice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term infants (weight: 2500–4000 g) who required phototherapy for jaundice of unknown cause Exclusion Criteria: Infants with congenital anomalies5ˈ minute Apgar score <7ˈ contraindications for massage (sores, cuts, burns, infectious rashes, dislocations, hyperthermia, or swollen joints).

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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 Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences,Daneshgah St

City

Mashhad

Postal code

9138813944

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

88469

Health conditions studied

1

Description of health condition studied

neonatal hyperbilirubinemia

ICD-10 code

59.9

ICD-10 code description

Neonatal Jaundice

Primary outcomes

1

Description

Unknown hyperbilirubinemia

Timepoint

At admision

Method of measurement

Questionnaire, Laboratory Test

Secondary outcomes

1

Description

Bilirubine level

Timepoint

at admision, phototherapy, discharge time

Method of measurement

Diazo test

2

Description

Duration of phototherapy

Timepoint

Discharge time

Method of measurement

Hours

Intervention groups

1

Description

Infants in the control group received traditional phototherapy and intensive care.

Category

Treatment - Other

2

Description

Infants in the intervention group received massage in addition to conventional phototherapy and intensive care. Massage was performed thrice daily (every 8 h) for 30 min each. Using gentle pressure, the researcher usually massaged different parts of the body with the soft parts of the fingers of both hands. Six organs of the body were massaged) lower limbs, upper limbs, abdomen, chest, back, and head and neck (.

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Hassan boskabad
Street address
Neonatal Unite, Ghaem Hospital, Ahmadabad ST.
City
mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi, Vice chancellor for research
Street address
Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgaj St
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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, Mashhad 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
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Najmeh Alfi
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Person responsible for updating data

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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