Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of baby massage effects on billirubin level in patient with neonatal jaundice

Protocol summary

Summary

Objective: Evaluation of baby massage effects on billirubin level in patient with neonatal jaundice. Design: Randomized, single-blind, single-center, phase II trial. Setting and conduct: massage therapy and non-massage therapy is placed randomly into two groups. level of bilirubin is measured on the first, second, third and fourth day of hospitalization. Participants including major eligibility criteria: Inclusion criteria include Infants with neonatal jaundice have age between 2 to 14 days; exclusion criteria include preterm infants. Intervention: Infants in the intervention group will be underwent massage therapy and Infants in the control group will not be underwent massage therapy. main outcome measures variable: The level of total bilirubin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121610933N4**
Registration date: **2016-05-12, 1395/02/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-12, 1395/02/23

Registrant information

Name

Fatemeh Eghbalian

Name of organization / entity

Hamadan University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1822 3978

Email address

eghbalian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of baby massage effects on billirubin level in patient with neonatal jaundice

Public title

effects of baby massage on billirubin level in neonatal jaundice

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 2 to 14 days; full term newborn (gestational age between 38 to 40 weeks); weight of 2500 to 4000 gr; having indirect hyperbilirubinemia (TSB>16 mg/dl); absence of hemolysis, ABO or Rh incompatibility; negative coomb’s test; reticulocyte count less than 5%. Exclusion criteria: The neonates with sign of sepsis; electrolyte impairment; any congenital anomalies or disease; seizure; formula feeding; hemolytic disease and those who need exchange transfusion.

Age

From **2 days** old to **14 days** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **134**
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 Hamedan University of Medical Sciences
Street address
Mahdie Ave, Hamadan University of Medical Sciences, Hamadan, Iran.
City
Hamedan
Postal code
Approval date
2015-06-23, 1394/04/02
Ethics committee reference number
IR.umsha.REC.1394.140

Health conditions studied

1

Description of health condition studied
Neonatal jaundice
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Total billirubin
Timepoint
First, second, third and fourth day of hospitalization
Method of measurement
RA1000 Techinca

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group under massage therapy plus phototherapy
Category
Treatment - Other

2

Description
Control group without massage therapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beasat Hospital
Full name of responsible person
Fatemeh Eghbalian
Street address
Neonatal Ward, Besat hospital, Motahari Ave, Hamedan, Iran.
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hamedan University of Medical Sciences
Full name of responsible person
Heydar Tavilani
Street address
Mahdie Ave, Hamadan University of Medical Sciences, Hamadan, Iran.
City
Hamedan
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, Hamedan 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

Hamedan University of Medical sciences

Full name of responsible person

Fatemeh Eghbalian

Position

Professor of Neonatology

Other areas of specialty/work

Street address

Neonatal Ward, Besat hospital, Motahari Ave, Hamedan, Iran.

City

hamedan

Postal code

Phone

+98 81 1822 3978

Fax

Email

eghbalian_fa@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical sciences

Full name of responsible person

Fatemeh Eghbalian

Position

Professor of Neonatology

Other areas of specialty/work

Street address

Neonatal Ward, Besat hospital, Motahari Ave, Hamedan, Iran.

City

Hamedan

Postal code

Phone

+98 81 1822 3978

Fax

Email

eghbalian_fa@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical sciences

Full name of responsible person

Fatemeh Eghbalian

Position

Professor of Neonatology

Other areas of specialty/work

Street address

Bessat Hospital, Motahari Ave, Hamedanl Iran

City

Hamedan

Postal code

Phone

+98 81 1822 3978

Fax

Email

eghbalian@umsh.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