

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

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

#### Protocol summary

##### Summary

Objective: Evaluation of baby massage effects on bilirubin 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 bilirubin level in patient with neonatal jaundice

##### Public title

effects of baby massage on bilirubin 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 Technica

**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**  
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Neonatal Ward, Besat hospital, Motahari Ave,  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*