

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparative investigating the effect of reflexology and neonatal massage on the level of bilirubin in hospitalized neonates with hyperbilirubinemia

#### Protocol summary

##### Study aim

Comparison of the effect of two methods of massage and reflexology on the bilirubin level of newborns with hyperbilirubinemia treated with phototherapy admitted in Hospital

##### Design

This study is a randomized clinical trial with control group and samples will be divided into two intervention groups and one control group.

##### Settings and conduct

After receiving written consent from the infant's parents, the serum bilirubin level of the infant was obtained by taking the venous blood sample before Phototherapy is determined in all three groups (massage, reflexology and control intervention). Then the amount of bilirubin will be measured again within 24 hours and 48 hours. Neonates receive routine treatment for jaundice (phototherapy) in all three groups. device.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are term neonates with indirect hyperbilirubinemia and congenital abnormalities and clear gastrointestinal disorders. Exclusion criteria are any risk factors such as hemolysis, septicemia, asphyxia, pathologic jaundice (day 1 jaundice) and infection

##### Intervention groups

In the first intervention group, in addition to phototherapy, massage therapy and in the second intervention group, in addition to phototherapy, reflexology will be performed. The control group will receive only phototherapy.

##### Main outcome variables

Bilirubin level

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180206038642N3**

Registration date: **2019-08-30, 1398/06/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-30, 1398/06/08**

Update count: **0**

#### Registration date

2019-08-30, 1398/06/08

#### Registrant information

##### Name

Fatemeh Abdoli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

abdoli\_f@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-07-23, 1398/05/01

#### Expected recruitment end date

2019-12-22, 1398/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparative investigating the effect of reflexology and neonatal massage on the level of bilirubin in hospitalized

neonates with hyperbilirubinemia

**Public title**

The effect of reflexology and massage on neonatal jaundice

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

having indirect hyperbilirubinemia. Term baby (42-37 weeks) Apgar at birth 8-10 Infants weighing at least 2500 grams to 4000 grams No prohibition of foot massage (Edema, tissue damage, skin infections, cutaneous rash, fractures and vascular disorders) Failure to pass meconium

**Exclusion criteria:**

Any risk factors such as hemolysis, septicemia, asphyxiation Pathologic icter (jaundice of the first day) Glucose 6-phosphate enzyme deficiency (G6PD) Congenital anomalies Infection (pneumonia, gastroenteritis, sepsis and bronchitis) Gastrointestinal obstruction Biliary atresia Diarrhea and child tanning during phototherapy Parental unwillingness to participate in the study disease such as congenital anomalies, neurological disorders, gastrointestinal and genetic disorders Perform blood transfusion

**Age**

From **3 days** old to **15 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling will be made available, purposeful and gradual. Samples will be randomly divided into two intervention groups (reflexology and massage) and a control group. In order to prevent communication and inform the parents of the three groups, sampling will be done weekly, so that it will first be determined by lottery which groups will be evaluated in the first, second and third weeks. Then sampling will continue until the desired number is reached.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Rafsanjan University of Medical Sciences

**Street address**

Blvd. Hazrat Ali ibn Abitaleb

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Approval date**

2019-05-15, 1398/02/25

**Ethics committee reference number**

IR.RUMS.REC.1398.029

**Health conditions studied****1****Description of health condition studied**

Hyperbilirubinemia

**ICD-10 code**

P59.9

**ICD-10 code description**

Neonatal jaundice, unspecified

**Primary outcomes****1****Description**

The amount of bilirubin

**Timepoint**

Before the intervention and 24 hours and 48 hours after the intervention

**Method of measurement**

Laboratory result

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In the massage therapy group, babies receive massage programs in addition to phototherapy, for three consecutive days for 20 to 15 minutes a day.

**Category**

Treatment - Other

## 2

### Description

Intervention group: In the reflexology group, neonates, in addition to phototherapy, according to the study, receive reflexology program for two consecutive days and three times a day, each 20-15 days in the intestine and colon.

### Category

N/A

## 3

### Description

Control group: In the control group, only phototherapy will be performed.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali Ibn Abi Talib Hospital in Rafsanjan

##### Full name of responsible person

Negar Nikzad

##### Street address

Boulevard of Imam Ali ibn Abitaleb

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

##### Phone

+98 34 3425 5900

##### Email

abdoli\_f@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

fateme Abdoli

##### Street address

Boulevard of Imam Ali ibn Abitaleb

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

##### Phone

+98 34 3425 5900

##### Email

abdoli\_f@yahoo.com

##### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Rafsanjan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Fateme Abdoli

##### Position

Faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

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Ali ibn Abi Talib Blvd.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rafsanjan University of Medical Sciences

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##### Latest degree

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Publish the results through a thesis and a valid scientific journal

**When the data will become available and for how long**

Max. Up to one year

**To whom data/document is available**

Medical and Nursing Society

**Under which criteria data/document could be used**

Use of results in research and clinical applications

**From where data/document is obtainable**

Via telephone and email

**What processes are involved for a request to access data/document**

Requests for correspondence will be made upon request

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Fateme Abdoli

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

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