

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Clinical trial of effect of touch as a complement for phototherapy on the reduction level of bilirubin in icteric newborns

#### Protocol summary

##### Summary

Objectives: Survey of effect of touch as a complement for phototherapy on the reduction level of bilirubin in icteric newborns Design: Not blinded randomized clinical trial Setting and conduct: 60 icteric newborns will be divided into two groups, intervention(n=30) and control(n=30).The intervention group moreover phototherapy will be touched, but the control group were only treated with phototherapy. Major Inclusion and Exclusion criteria: Inclusion criteria: Full-term newborns weighing over 2000 grams; with Apgar score between 8-10; exclusive breastfeeding with mothers milk and having bilirubin greater than 12 milligrams per deciliter Exclusion criteria: Preterm infants with birth weight less than 2000 grams; having skin diseases; blood disorders; heart problems; hypothyroidism Intervention: The process of touching will be done by a trained person, 4 times a day, for 15 minutes, for two days Main outcome measures (variables): Bilirubin levels of blood

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2015070122583N2**

Registration date: **2016-02-06, 1394/11/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-02-06, 1394/11/17

##### Registrant information

###### Name

Mohsen Shoja

###### Name of organization / entity

Esfarayen Faculty of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 85 3722 2469

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Esfarayen Faculty of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-06-21, 1395/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of effect of touch as a complement for phototherapy on the reduction level of bilirubin in icteric newborns

##### Public title

Effect of touch as a complement for phototherapy on the reduction level of bilirubin in icteric newborns

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: full-term newborns weighing over 2000 grams; with Apgar score between 8-10; exclusive breastfeeding with mothers milk and having bilirubin greater than 12 milligrams per deciliter Exclusion criteria: preterm infants with birth weight less than 2000 grams; having skin diseases; blood disorders; heart

problems; hypothyroidism.

#### Age

To 6 months old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 60

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Blocking randomization

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfarayen\*Faculty of Medical Sciences

##### Street address

Esfarayen Faculty of Medical Sciences, Emam Reza Street, Esfarayen, North Khorasan

##### City

Esfarayen

##### Postal code

#### Approval date

2016-01-06, 1394/10/16

#### Ethics committee reference number

IR.ESFARAYENUMS.REC.1394.10

## Health conditions studied

### 1

#### Description of health condition studied

Hyperbilirubinemia

#### ICD-10 code

P 59.9

#### ICD-10 code description

Neonatal jaundice, unspecified

## Primary outcomes

### 1

#### Description

Bilirubin in blood of newborns

#### Timepoint

Every 24 hours

#### Method of measurement

milligrams per deciliter

## Secondary outcomes

### 1

#### Description

Discharge of newborns

#### Timepoint

day

#### Method of measurement

a day

## Intervention groups

### 1

#### Description

Intervention group: In addition to doing phototherapy that will be done for 90 minutes and will be stopped for 30 minutes alternately, newborn's body touched by a trained person, 4 times a day , each time for 15 minutes for two days

#### Category

Other

### 2

#### Description

control group: Phototherapy will be done for 90 minutes and will be stopped for 30 minutes alternately.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Khomeini Hospital of Esfarayen

##### Full name of responsible person

Mohammad Shoja

##### Street address

Emam Khomeini Hospital, Esfarayen, North Khorasan

##### City

Esfarayen

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Esfarayen faculty of

Medical Sciences, Esfarayen  
**Full name of responsible person**  
 Mohsen Shoja  
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 Street, Esfarayen, North Khorasan  
**City**  
 Esfarayen  
**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 of Esfarayen faculty of  
 Medical Sciences, Esfarayen  
**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

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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*