

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Esfarayen faculty of

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 Mohsen Shoja
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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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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