

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Intermittent versus continuous phototherapy for the treatment of neonatal non-hemolytic moderate hyperbilirubinemia in infants more than 37 weeks of gestational age: a randomized controlled trial

Protocol summary

Summary

This prospective randomized case control study is performed on 60 neonates with indirect hyperbilirubinemia who are admitted to neonatal ward in Loghman hospital in Tehran, Iran. The neonates are randomly divided into two groups, 30 neonates in continuous (Group I) and 30 in intermittent (Group II) phototherapy group. Then we compare the primary and secondary outcomes in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112225184N1**
Registration date: **2017-03-17, 1395/12/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-17, 1395/12/27

Registrant information

Name

Roya Taheri Tafti

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8828 8037

Email address

royataheritafti@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intermittent versus continuous phototherapy for the treatment of neonatal non-hemolytic moderate hyperbilirubinemia in infants more than 37 weeks of gestational age: a randomized controlled trial

Public title

Intermittent versus continuous phototherapy for the treatment of neonatal non-hemolytic moderate hyperbilirubinemia in infants more than 37 weeks of gestational age: a randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

This study has been performed on 60 neonates with indirect hyperbilirubinemia; inclusion criteria are gestational age above 37 weeks and absence of other concomitant diseases such as hemolysis and upper limit of their bilirubin are 18 mg/dl.

Age

From **3 days** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee for Ethics in Biomedical Research

Street address

The headquarters of the Ministry of Health and
Medical Education-Sharak Gharb - Tehran

City

Tehran

Postal code

Approval date

2016-11-13, 1395/08/23

Ethics committee reference number

66001089/27

Health conditions studied

1

Description of health condition studied

Icter

ICD-10 code

R17

ICD-10 code description

P55-59

Primary outcomes

1

Description

Bilirubin

Timepoint

pretreatment and 6 hours after phototherapy

Method of measurement

blood sampling

2

Description

melatonin

Timepoint

after depletion of bilirubin

Method of measurement

special kit and blood sampling

Secondary outcomes

1

Description

kernicterus

Timepoint

during of treatment

Method of measurement

sign and symptoms

2

Description

complications

Timepoint

at the end of treatment

Method of measurement

observation

3

Description

duration of phototherapy

Timepoint

at the end of treatment

Method of measurement

observation

4

Description

hospital lenght of stay

Timepoint

at the end of treatment

Method of measurement

observation

5

Description

melatonin

Timepoint

at the end of treatment

Method of measurement

blood sampling

Intervention groups

1

Description

Continuous phototherapy for control group

Category

Treatment - Other

2

Description

Intermittent phototherapy for intervention group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman hosaital

Full name of responsible person

Dr Taheri

Street address

Loghman hosaital, Lashkar cossing, South Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Loghman Hospital

Full name of responsible person

Dr. Hasan Peyvandi

Street address

Loghman Hospital, Lashgar Cross. South Kargar St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Loghman Hospital

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

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Roya Taheri Tafti

Position

Assistant professor

Other areas of specialty/work

Street address

Loghman Hospital, Lashgar Cross. South Kargar St.

City

Tehran

Postal code

Phone

+98 218288037

Fax

Email

royataheritafti@sbmu.ac.ir;

royataheritafti@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Roya Taheri Tafti

Position

Assistant professor

Other areas of specialty/work

Street address

Loghman Hospital, Lashgar Cross. South Kargar St.

City

Tehran

Postal code

Phone

+98 21 5102 5000

Fax

Email

royataheritafti@sbmu.ac.ir;

royataheritafti@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Roya Taheri Tafti

Position

Assistant professor

Other areas of specialty/work

Street address

Loghman Hospital, Lashgar Cross. South Kargar St.

City

Tehran

Postal code

Phone

+98 218288037

Fax

Email

royataheritafti@sbmu.ac.ir;

royataheritafti@yahoo.com

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