Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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; iInclusion criteria are gestational age above 37 weeks and absence of other concomittant 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 hosoital
Full name of responsible person
Dr Taheri
Street address
Loghman hosoital, 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
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Person responsible for updating data

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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