

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of cycled phototherapy with continuous phototherapy in treatment of jaundice in premature VLBW neonates

Protocol summary

Study aim

Comparison of Periodic Phototherapy with Continuous Phototherapy in the Treatment of VLBW Neonatal Jaundice in NICU ward

Design

Clinical trial with two groups with continuous phototherapy (control) and With parallel, two-way blind groups, randomized phase 1_2 on 150 patients, the rand function of Excel software was used for randomization.

Settings and conduct

Infants hospitalized in neonatal intensive care unit of Afzalipour Hospital in Kerman with jaundice less than one day have been selected and due to intubation or not, they are placed in two groups and then blinding is done for receiving permanent or periodic phototherapy among parents of infants, researcher, vanalisor assessor group according to the need for intervention in order to discontinue phototherapy in periodic type or receive phototherapy. Permanently do not go blind in case of excessive bilirubin increase

Participants/Inclusion and exclusion criteria

Entry requirements: Weight 1000 to 1500 g Not receiving previous phototherapy Need to receive phototherapy Age less than 24 hours Non-entry requirements: Known hemolytic disease Asphykisia Nonbacterial infection overt The existence of major anomalies Unstable conditions (pH of arterial blood less than 6.8 for more than 2 hours, stable bradycardia associated with hypoxia over 2 hours) Informed dissatisfaction of parents or legal guardian of the infant to enter the study

Intervention groups

The effect of phototherapy at 15 minutes per hour in infants weighing 1000-1500 grams hospitalized in NICU ward with control group receiving continuous phototherapy and comparing the efficacy and effects in both groups.

Main outcome variables

Treatment of Neonatal Jaundice

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211218053444N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Zahra Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8198

Email address

z.jamali@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-05, 1400/12/14

Expected recruitment end date

2022-06-09, 1401/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cycled phototherapy with continuous phototherapy in treatment of jaundice in premature VLBW neonates

Public title

Cycled phototherapy in treatment of neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Weight 1000 to 1500 grams Failure to receive previous phototherapy Need to receive phototherapy Age less than 24 hours

Exclusion criteria:

Known hemolytic disease Asphyxia Non-bacterial infection overt Existence of major anomalies Unstable conditions (arterial blood pH less than 6.8 for more than 2 hours, stable bradycardia associated with hypoxia for more than 2 hours) Unwanted consent of the baby's parents or legal guardian to enter the study

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

The Infants will be Admitted to the Study by Observing the Inclusion Criteria, Which will be Classified into two Groups, High Risk and Low Risk, based on the State of Intubation, and then Will Be Randomly Divided into two Groups with a Ratio of 1: 1. the First Group will Receive Continuous Phototherapy and the Other Group Will Receive Periodic Phototherapy Beds for 15 Minutes Per Hour.

Blinding (investigator's opinion)

Double blinded

Blinding description

Parents of infants participating in the study will be blinded in one of two groups after obtaining consent .Clinical caregivers are not blinded due to direct involvement with the baby and the need to discontinue phototherapy at the desired time. The researcher ,the assessor and the enlisor are blind in this study and extract the results from patient records

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

Ebn-e-Sina St., Jahad Blvd., Kerman

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2021-11-03, 1400/08/12

Ethics committee reference number

IR.KMU.AH.REC.1400.185

Health conditions studied

1

Description of health condition studied

Neonatal Jaundice

ICD-10 code

jaundice

ICD-10 code description

زردی نوزادان

Primary outcomes

1

Description

Neonatal jaundice rate

Timepoint

Fourteen days

Method of measurement

Serum bilirubin levels

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The effect of periodic phototherapy on VLBW neonates Control group: Effect of permanent phototherapy on VLBW neonates . Neonates will be classified into two groups of high risk and low risk based on intubation status and then randomly divided into two groups with a ratio of 1 to 1. The first group will undergo continuous phototherapy and the other group will be

subjected to periodic phototherapy bed for 15 minutes per hour. Serum bilirubin total levels (TSB) of newborns will be measured daily for up to seven days after birth and also on the day that phototherapy was administered or stopped in the second week after birth. Also, the average total hours of phototherapy will be recorded in two groups and will be used for statistical comparison. Light-emitting diode phototherapy lamps will be used to irradiate the blue light of the narrow spectrum. The irradiance intensity of phototherapy lamp will be pre-adjusted so that patients receive 22 $\mu\text{W}/\text{cm}^2/\text{nm}$ of light in low settings equal to 33 $\mu\text{W}/\text{cm}^2/\text{nm}$ in high settings. V wave delay in Brainstem auditory-evoked responses (BAERs), a neurotoxicity sensitive marker with bilirubin, is also measured.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Zahra Jamali

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Emam Blvd., Afzalipour Hospital .NICU

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Zahra Jamali

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information will be shared, but how it will be published will be announced later

When the data will become available and for how long

Information will be shared, but how it will be published will be announced later

To whom data/document is available

Information will be shared, but how it will be published will be announced later

Under which criteria data/document could be used

Information will be shared, but how it will be published will be announced later

From where data/document is obtainable

Information will be shared, but how it will be published will be announced later

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

Information will be shared, but how it will be published will be announced later

Comments