Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of cycled phototherapy with continuous phototherapy in treatment of jaundice in premature very low-birth-weight (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 age 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

Inclusion criteria: Weight 1000 to 1500 g (GA: 28-32 wks) Not receiving previous phototherapy Need to receive phototherapy Age less than 24 hours Exclusion criteria: 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

Reducing phototherapy complications by reducing phototherapy time

General information

Reason for update

We forgot to enter the age range. To prevent IUGR babies from entering, we decided to specify the age range.

Acronym

IRCT registration information

IRCT registration number: **IRCT20211218053444N1**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **prospective**

Last update: **2026-06-22, 1405/04/01**
Update count: **1**

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 very low-birth-weight (VLBW) neonates

Public title
Cycled phototherapy in treatment of neontal jaundice
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Weight 1000 to 1500 grams (GA: 28-32 wks) 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
Jahad Blvd., Ebn-e-Sina St.,
City
Kerman
Province
Kerman
Postal code
7619813159
Approval date
2021-11-04, 1400/08/13
Ethics committee reference number
IR.KMU.AH.REC.1400.185

Health conditions studied

1

Description of health condition studied
Neonatal Jaundice
ICD-10 code
P59.8
ICD-10 code description
Neonatal jaundice from other specified causes

Primary outcomes

1

Description
Neonatal jaundice rate
Timepoint
The primary outcomes were the mean peak TSB levels and total hours of phototherapy during the first 14 days of life.
Method of measurement
Serum bilirubin levels

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The effect of intermittent phototherapy on very low birth weight infants.
Category
Treatment - Devices

2

Description
Control group: The effect of continuous phototherapy in very low birth weight infants. Infants will be classified into high-risk and low-risk groups based on their intubation status and then randomly assigned to one of the two groups in a 1:1 ratio. The first group will receive continuous phototherapy and the other group will receive intermittent phototherapy for 15 minutes per hour. The infants' total serum bilirubin levels will be measured daily for seven days after birth and also on the day phototherapy is administered or stopped in the second week after birth. If more than one total serum bilirubin sample was taken per day, the total serum bilirubin level that was closest to 7 a.m. and the highest total serum bilirubin level of the day will both be recorded. The average total hours of phototherapy in the two groups will also be recorded and used for statistical comparison. Light-emitting diode phototherapy lamps will be used to emit narrow-spectrum blue light. The intensity of the phototherapy lamp will be preset so that patients receive 22 microwatts/cm2/nm of light at the low setting and 33 microwatts/cm2/nm at the high setting. The V-wave latency of the auditory brainstem evoked responses, a sensitive marker of bilirubin neurotoxicity, is also measured.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Zahra Jamali
Street address
Imam Khomeini Highway
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 3132 8000
Email
z.jamali@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hamid Sharifi
Street address
The beginning of Haft Bagh Alavi axis
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 3132 8000
Email
z.jamali@kmu.ac.ir
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
Pediatrics
Street address
Imam Highway
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
031328000
Email
z.jamali@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Zahran Jamali

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Imam Highway

City
Kerman

Province
Kerman

Postal code
7616913355

Phone
+98 34 3132 8000

Email
z.jamali@kmu.ac.ir

Person responsible for updating data

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
Pediatrics

Street address
Imam Highway

City
Kerman

Province
Kerman

Postal code
7616913355

Phone
009831328000

Email
z.jamali@kmu.ac.ir

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