Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Melatonin Administration as an Adjuvant Therapy in Preterm Infants with Neonatal Jaundice

Protocol summary

Study aim
The overall objective of the present study will be to investigate the effect of melatonin supplementation as adjuvant therapy in preterm neonates with neonatal jaundice.

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 60 patients. To randomize the research samples, we will use the limited randomization method of the block randomization type.

Settings and conduct
This study is a randomized and double-blind clinical trial that will be conducted with a focus on preterm infants with neonatal jaundice in Mofid Children's Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Gestational age 32-37 weeks 2. Serum bilirubin level below exchange transfusion threshold 3. Indirect hyperbilirubinemia 4. Postnatal age under 30 days Exclusion criteria: 1. Underlying diseases and congenital anomalies in the neonate 2. Any signs of neonatal sepsis or other infections 3. Signs and risk factors of hemolysis 4. Acute or chronic respiratory diseases

Intervention groups
The control group neonates will only receive phototherapy, while the case group will receive 5.0 mg/kg/day oral melatonin drops in addition to phototherapy.

Main outcome variables
Serum bilirubin level (mg/dL)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231210060317N1**
Registration date: **2023-12-24, 1402/10/03**
Registration timing: **prospective**
Last update: **2023-12-24, 1402/10/03**
Update count: **0**

Registration date
2023-12-24, 1402/10/03

Registrant information

Name
Farzaneh Ahmadi Khatiri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2290 4603

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ahmadikhatiri@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Melatonin Administration as an Adjuvant Therapy in Preterm Infants with Neonatal Jaundice

Public title
Melatonin Administration as an Adjuvant Therapy in Preterm Infants with Neonatal Jaundice

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 32-37 weeks Serum bilirubin level below exchange transfusion threshold Indirect hyperbilirubinemia Postnatal age under 30 days

Exclusion criteria:

Underlying diseases and congenital anomalies in the neonate Any signs of neonatal sepsis or other infections Signs and risk factors of hemolysis Acute or chronic respiratory diseases

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the study samples, we will use restricted randomization, specifically block randomization. All block sizes will be equal, using blocks of 4 (including 2 neonates in the control group and 2 in the melatonin group).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, after explaining the objectives of the research to the parents and obtaining written consent, the infants were randomly assigned to one of the two groups of case and control. Each patient is assigned a code, and parents are unaware of whether their child is in the control group or the case. In the same way, the researcher only had the task of allocating patients to two groups number one and two, and is not aware of the definition of groups one and two. After assigning the patient to one of the desired groups, the necessary intervention is carried out by a specialist in the neonatal department, and the results are evaluated and recorded by the evaluation, which has the task of collecting the results of the results based on the patient's code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Daneshjou Blvd, Shahid Beheshti University of medical sciences, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1983535511

Approval date

2023-09-30, 1402/07/08

Ethics committee reference number

IR.SBMU.MSP.REC.1402.371

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.0

ICD-10 code description

Neonatal jaundice associated with preterm delivery

Primary outcomes

1

Description

Serum bilirubin level (mg/dL)

Timepoint

Serum bilirubin levels will be measured in both groups before the intervention (T0), on the first day (T1), and on the second day (T2) after the intervention.

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Neonates in this group will receive 0.5 mg/kg/day oral melatonin drops in addition to phototherapy.

Category

Treatment - Drugs

2

Description

Control group: Neonates in this group will only receive phototherapy.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid Children's Hospital

Full name of responsible person
Farzaneh Ahmadi Khatiri

Street address
Shariati Ave, Mofid Children Hospital, Neonatology department.

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Tehran

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1546815514

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+98 21 2222 7033

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Ahmadikhatiri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Velenjak, Daneshjou Blvd, Shahid Beheshti University of Medical sciences, Deputy of research and technology.

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farzaneh Ahmadi Khatiri

Position
Neonatology fellowship

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Shariati Ave, Mofid Children's hospital, Tehran, Iran.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, after completing the study, all potential data will be shared with other researchers through the Research Gate data-sharing system after de-identifying the patients.

When the data will become available and for how long

Access will start from the time the results are printed.

To whom data/document is available

The data will be publicly available to all interested parties through the link created on the researcher's Research Gate page.

Under which criteria data/document could be used

The use of research data for future studies by referring to the main published article of the present research will be unimpeded.

From where data/document is obtainable

The data will be transparently accessible through the link included in the final article.

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

The data will be transparently accessible through the link included in the final article.

Comments