

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of melatonin in the prevention of retinopathy of prematurity in preterm neonates

Protocol summary

Study aim

Determining the effect of melatonin on prevention of retinopathy of prematurity

Design

A clinical trial with parallel groups, double-blinded, randomized (permuted block randomization), phase 3 on 60 neonates with retinopathy of prematurity, using www.sealedenvelope.com for randomization.

Settings and conduct

This study is performed in Ali Asghar, Akbarabadi and Firoozabadi Hospital. neonates with retinopathy of prematurity are randomly assigned into two groups. In the intervention group, neonates take melatonin. In the control group, neonates get routine treatment. In this study, investigator and physician did not know the type of medication they received.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Parents satisfaction to participate in the study, Premature newborns under 34 weeks, Lack of congenital anomalies, Lack of genetic disorder, metabolic disorder or suffering from TORCH, Lack of intraventricular hemorrhage (grade 3 and 4). Exclusion criteria: intraventricular hemorrhage (grade 3 and 4) during patients follow up, Incidence of gastrointestinal complications such as NEC during treatment if it is not possible to take the medicine orally, Taking less than 14 days of melatonin.

Intervention groups

In the Intervention group neonates receive melatonin softgel (Dana Company, Iran) daily at dosage of 3 mg/kg/day until 37 weeks and in the control group neonates get only routine treatment.

Main outcome variables

Stopping abnormal development of retinal vessels and nerves

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211226053528N2**

Registration date: **2022-09-21, 1401/06/30**

Registration timing: **retrospective**

Last update: **2022-09-21, 1401/06/30**

Update count: **0**

Registration date

2022-09-21, 1401/06/30

Registrant information

Name

Nastaran Khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

khosravi.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin in the prevention of retinopathy of prematurity in preterm neonates

Public title

The effect of melatonin in the prevention of retinopathy of prematurity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Parents satisfaction to participate in the study
Premature newborns under 34 weeks
Lack of congenital anomalies
Lack of genetic disorder, metabolic disorder or suffering from TORCH
Lack of intraventricular hemorrhage (grade 3 and 4)

Exclusion criteria:

Intraventricular hemorrhage (grade 3 and 4) during patients follow up
Incidence of gastrointestinal complications such as NEC during treatment if it is not possible to take the medicine orally.
Taking less than 14 days of melatonin

Age

From **1 day** old to **7 days** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method is used and the block size is 6. The website <https://www.sealedenvelope.com> is used to generate random sequences. Each participant is assigned a sequence. Then, each participant was randomly assigned to one of the arms of the study (A or B). The random sequence is given to the epidemiologist of the study, and every patient who enters the study, the doctor will contact him to find out whether the person will enter group A or B.

Blinding (investigator's opinion)

Double blinded

Blinding description

After random allocation, the randomized list will be placed in sealed envelopes. In this way, the first doctor will be blinded to assigning people to treatment groups. Regarding to ophthalmologist does not know about the treatments provided, he will be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Next to the Milad Tower

City

Tehran

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Postal code

1449614535

Approval date

2021-12-13, 1400/09/22

Ethics committee reference number

IR.IUMS.FMD.REC.1400.542

Health conditions studied

1

Description of health condition studied

Retinopathy of Prematurity

ICD-10 code

H35.1

ICD-10 code description

Retinopathy of prematurity

Primary outcomes

1

Description

Stopping of abnormal blood vessels formation in the retina

Timepoint

End of 37 weeks and end of 44 weeks

Method of measurement

Examination by retina fellowship and with ophthalmoscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Babies receive melatonin softgel (Nutralab under license of Canada) daily at dosage of 3 mg/ kg/day until 37 weeks.

Category

Treatment - Drugs

2

Description

Control group: This group of neonates gets only routine treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

Hamid Khalilian

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Molavi St, Molavi (cross)

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Recruitment center

Name of recruitment center

Aliasghar Children's Hospital

Full name of responsible person

Hamid Khalilian

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Recruitment center

Name of recruitment center

Firoozabadi Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Hamid Khalilian

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable