# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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:ntraventricular 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 neonatess gets 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)

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+98 21 2304 6253

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**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
**Province**
Tehran
**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 neonatess 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
**Street address**
Molavi St, Molavi (cross)
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**2**

**Recruitment center**
**Name of recruitment center**
Aliasghar Children's Hospital
**Full name of responsible person**
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No. 193, Vahid dastgerdy Ave, Modares highway, Aliasghar Children Hospital
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**3**

**Recruitment center**
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## Sponsors / Funding sources

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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
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Hamid Khalilian
**Position**
Fellow
**Latest degree**
Specialist
**Other areas of specialty/work**
Pediatrics

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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