

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigation of the oral (propranolol) and topical beta-blocker (Timolol eye drop) drugs in preventing the exacerbation of retinopathy of prematurity of stage 2 and above in premature neonates

#### Protocol summary

##### Study aim

Investigation of the oral (propranolol) and topical beta-blocker (Timolol eye drop) drugs in preventing the exacerbation of retinopathy of prematurity of stage 2 and greater in premature neonates of Kamali Hospital in Karaj in 2022 and 2023

##### Design

The clinical trial has three parallel groups (two intervention groups with propranolol and timolol eye drops) and a control group, double-blind, randomized on 75 patients (25 patients in each group), phase 2. In this study, allocation Randomization will be done using permuted block balance randomization technique and STATA software will be used .

##### Settings and conduct

This study will be done as a clinical trial in Kamali Karaj Teaching Hospital in 2022-2023. According to the sample size formula, 75 people will be included in the study and the patients will be divided into three groups. An oral propranolol group and timolol eye drops group and usual treatment. . The study will be done in a double blind way so that the doctor and Nurses are aware of patients, but ophthalmologists and epidemiologists are not aware.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Gestational age less than 34 weeks  
2. Premature infants aged 26 to 34 weeks who underwent eye examination from the fourth to the twelfth week of birth and it was determined that 2 stage ROP and above are Exclusion Criteria: 1. Infants with congenital or acquired cardiac anomalies 2. Renal failure 3. Cerebral hemorrhage 4. ROP stage 1 5. Unstable hemodynamics 6. Sepsis

##### Intervention groups

Patients will be divided into three groups. One group will receive oral propranolol 0.5 dose/kg/mg every 8 hours in addition to the standard treatment, and the other group will receive timolol eye drops 0.5 drops twice a day, and

the other group will receive the usual treatment.

##### Main outcome variables

Progression rate of stage 3 retinopathy of prematurity in stage 2 retinopathy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230526058300N1**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

##### Registration date

2023-12-30, 1402/10/09

##### Registrant information

##### Name

Elnaz Abdollahi

##### Name of organization / entity

The Alborz university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6556 7735

##### Email address

elnazabdollahii@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-22, 1402/10/01

##### Expected recruitment end date

2024-02-20, 1402/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of the oral (propranolol) and topical beta-blocker (Timolol eye drop) drugs in preventing the exacerbation of retinopathy of prematurity of stage 2 and above in premature neonates

**Public title**

Investigation of beta-blockers in preventing the exacerbation of retinopathy of prematurity

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age less than 34 weeks Premature infants between 26 weeks and 34 weeks, who underwent ophthalmic examination from the fourth to the twelfth week of birth and it was determined that they have stage 2 ROP and above.

**Exclusion criteria:**

Infants with congenital or acquired cardiac anomalies ROP stage 1 Unstable hemodynamic

**Age**

From **189 days** old to **224 days** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, random allocation for placement in Each group will receive the intervention at the standard time using the block balance permuted randomization technique . According to these blocks considered in this study, there will be six blocks. using software STATA will generate a chain of random numbers from 1 to 6 until the desired sample size is reached. Given that the total number of states for Receiving medicine in blocks of 6 is 6 if the number produced is more than 6, regardless of the next number. will be produced.Preparation of random allocation sequences of drug groups and placing them in sealed envelopes (confidential) and numbering with a 5-digit serial number by a third party who is not involved in the design of the study All envelopes will have a 5-digit serial number that will be opened immediately after the patients enter the study. And the patients will be divided into three groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participating parents and participants do not know in which group are located. Eye examinations done by only one ophthalmologist. The doctor will take care and the ophthalmologist will not inform which group the infant is in

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz university of medical Sciences

**Street address**

45 metri Golshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

3198764653

**Approval date**

2023-12-02, 1402/09/11

**Ethics committee reference number**

IR.ABZUMS.REC.1402.259

**Health conditions studied****1****Description of health condition studied**

Retinopathy of prematurity

**ICD-10 code**

H35.13

**ICD-10 code description**

Retinopathy of prematurity, stage 2

**Primary outcomes****1****Description**

Determining the progression rate of retinopathy of prematurity 3 stage in babies with retinopathy 2 stage

**Timepoint**

weekly examination by ophthalmologist until discharge

**Method of measurement**

Retcam imaging system II

## Secondary outcomes

### 1

#### Description

The rate of complete recovery of retinopathy of prematurity in infants with stage 2 retinopathy

#### Timepoint

Weekly examination by Ophthalmologist

#### Method of measurement

Retcam imaging system II

## Intervention groups

### 1

#### Description

Intervention group: they receive oral propranolol 0.5 dose/kg/mg every 8 hours in addition to the standard treatment. We dissolve the propranolol tablet in the form of powder in 5% dextrose and give it to the baby after eating milk.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Timolol eye drops 0.5 drops twice a day

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Receiving the usual treatment for ROP means patient follow-up until complete recovery and regression of ROP or the need for intraocular injection of Avastin, surgery, laser therapy

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamali hospital Karaj

##### Full name of responsible person

Dr Hani Milani

##### Street address

Shahid Beheshti

##### City

Karaj

##### Province

Alborz

##### Postal code

3819693345

##### Phone

+98 26 3222 2021

#### Email

hanimilani@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Dr Mahmoud Bakhtiari

##### Street address

45 metri Golshahr

##### City

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3198764653

##### Phone

+98 28 3464 3705

##### Email

Research@abzums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Karaj 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

Karaj University of Medical Sciences

##### Full name of responsible person

Dr Hani Milani

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

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## Person responsible for scientific inquiries

### Contact

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Assistant professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Karaj University of Medical Sciences  
**Full name of responsible person**  
Dr Elnaz Abdollahi

**Position**  
Pediatrics Resident  
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Medical doctor  
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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

Undecided - It is not yet known if there will be 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