

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

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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

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45 metri Golshahr

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for updating data

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Dr Elnaz Abdollahi

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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