Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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 Sceiences
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
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Sponsors / Funding sources

1

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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
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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