

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluating the effect of oral Propranolol in preventing the progression of retinopathy of prematurity

Protocol summary

Study aim

Evaluating the effect of oral Propranolol in preventing of the progression of retinopathy of prematurity

Design

1. Proposal approval 2. Taking the code of ethics 3. Data collection 4. Data analysis 5. Final report

Settings and conduct

Premature neonates with GA less than 32 weeks or body weigh less than or equal to 1500 grams who are admitted to Alavi or Buali hospital NICU in Ardabil . As part of the screening protocol, these babies undergo retinal examination. In this research, infants with stage 1 or higher of retinopathy of prematurity, but without indication for treatment, will be included . They will be randomly assigned to either the intervention group or the control group.The intervention group will receive oral Propranolol at a dosage of 0.5 mg per kilogram every 8 hours until the completeion of retinal vessels or discharge. It is important to note that Propranolol may affect blood pressure, blood sugar levels, and heart rate. the control group will receive an equal amount of distilled water as a placebo. Both groups will undergo regular retinal examinations by a doctor following the protocol, and any changes observed during the process will be documented.

Participants/Inclusion and exclusion criteria

Infants who are admitted to the neonatal intensive care unit of Alavi or Buali Hospital in Ardabil, with a GA of less than 32 weeks or a birth weight below 1500 grams, who require weight gain. and have retinopathy of prematurity stage 1 or higher during examination, which does not need any intervention.

Intervention groups

Infants who have retinopathy of prematurity at stage 1 or higher but do not require any treatment for this condition.

Main outcome variables

Retinal vascularization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230717058817N1**

Registration date: **2023-07-24, 1402/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-24, 1402/05/02**

Update count: **0**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

Amin Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 2827

Email address

amin.najafi.dr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of oral Propranolol in preventing the progression of retinopathy of prematurity

Public title

Evaluating the effect of oral Propranolol in preventing the progression of retinopathy of prematurity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infants , with a gestational age of less than 32 weeks or a birth weight below 1500 grams,

Exclusion criteria:**Age**

From **1 month** old to **6 months** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

66 qualified neonates will be assigned to two groups of 33 people by random block allocation method (blocks of four). in this study, the block randomization method will be used so that the numbers in all groups be equal .

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ardabil University of Medical Sciences

Street address

Artesh Street

City

Ardabil

Province

Ardabil

Postal code

8599156189

Approval date

2022-10-15, 1401/07/23

Ethics committee reference number

IR.ARUMS.MEDICINE.REC.1401.080

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

retinopathy of prematurity

ICD-10 code

H35.103

ICD-10 code description

Retinopathy of prematurity, unspecified, bilateral

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

Retinal vascularization

Timepoint

Weekly

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group will receive oral Propranolol at a dosage of 0.5 mg per kilogram every 8 hours (24 doses) until the completion of retinal vessels or discharge. It is important to note that Propranolol may affect blood pressure, blood sugar levels, and heart rate.

Category

Treatment - Drugs

2**Description**

Control group: the control group will receive an equal amount of distilled water. Both groups will undergo regular retinal examinations by a doctor following the protocol, and any changes observed during the process will be documented.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alavi hospital

Full name of responsible person

Amin Najafi

Street address

Alavi hospital

City

Ardabil
Province
Ardabil
Postal code
8599156189
Phone
+98 45 3325 2827
Email
amin.najafi.dr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Amin Najafi
Street address
Ardabil-Ardabil University of Madical Sciences
City
Ardabil
Province
Ardabil
Postal code
56189-85991
Phone
+98 45 3352 2247
Email
amin.najafi.dr@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Amin Najafi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work

Ophthalmology
Street address
Artesh Street
City
Ardabil
Province
Ardabil
Postal code
8599156189
Phone
+98 45 3325 2827
Email
amin.najafi.dr@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Amin Najafi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Artesh Street
City
Ardabil
Province
Ardabil
Postal code
8599156189
Phone
+98 45 3325 2827
Email
amin.najafi.dr@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Amin Najafi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Artesh Street
City
Ardabil
Province
Ardabil
Postal code
8599156189

Phone

+98 45 3325 2827

Email

amin.najafi.dr@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We will decide on this later

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available