

# 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**  
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**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**  
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**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**  
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**Other areas of specialty/work**  
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**Postal code**  
8599156189

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**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