

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the efficacy of oral propranolol in prevention of severe Retinopathy of Prematurity : A Randomized Clinical Trial

Protocol summary

Study aim

Investigating the efficacy of oral propranolol in prevention of severe Retinopathy of Prematurity

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients. Excel software rand function is used for randomization.

Settings and conduct

In this study, preterm infants admitted to the neonatal intensive care unit of Imam Reza (AS) Hospital in Kermanshah, with gestational age ≤ 34 weeks or have a birth weight of ≤ 2000 g, and their ophthalmic examination confirms the diagnosis of grade 1 or 2 retinopathy enter the study and randomly enrolled in one of two groups, both groups are evaluated and compared for improvement or progression to higher ROP degree (grade 3 or higher) and the need for invasive treatments including laser therapy and intraocular injection of Avastin. Examinations continue until the retinal vascularity are complete or retinopathy regress.

Participants/Inclusion and exclusion criteria

Inclusion criteria: newborns with gestational age ≤ 34 weeks or birth weight ≤ 2000 g with retinopathy of prematurity stage I or II without plus disease. Exclusion criteria: newborns with congenital anomalies, heart diseases except PDA, recurrent bradycardia, eye malformations, acute renal failure, IVH grade II and III, acute sepsis

Intervention groups

In the case group, after diagnosis, oral propranolol with a dose of 0.5 mg/kg is started every 8 hours and the medication continues until Retinal vascularity completion on ophthalmic examination or the need for laser therapy. Infants in the control group receive routine care for premature infants and do not receive medication.

Main outcome variables

The rate of recovery from retinopathy of prematurity, the need for avastin injections, the need for laser treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101018004961N12**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

Name

Homa Babaei

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00988314276303 2292 داخلی

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homa_babaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-04, 1400/04/13

Expected recruitment end date

2022-05-02, 1401/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the efficacy of oral propranolol in prevention of severe Retinopathy of Prematurity : A Randomized Clinical Trial

Public title

Investigating the efficacy of oral propranolol in prevention of severe Retinopathy of Prematurity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

newborns with gestational age ≤ 34 weeks or birth weight ≤ 2000 g with retinopathy of prematurity stage I or II

Exclusion criteria:

Infants with congenital anomalies heart diseases except PDA recurrent bradycardia eye malformations acute renal failure IVH grade II and III, acute sepsis

Age

From **28 days** old to **120 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the random allocation method using the variable block method will be used. Volunteers participating in the study are assigned to the propranolol treatment group and the control group using block randomization with 4 and 6 blocks. The main tool in the design is a questionnaire that has been prepared by the project manager based on the main objectives and important and basic variables of the design. The collected data will be entered into SPSS statistical software version 20 and will be statistically analyzed. A random sequence generated by the computer and a design methodologist colleague will be used to assign intervention and placebo to participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

newborns and their parents, in both groups, will not know about their treatment (According to placebo consumption in the control group). The outcome assessor (retinal subspecialty) is also unaware of the allocation of infants to propranolol and control treatment groups (The study is double-blind). Determining this blinding is the responsibility of the neonatologist who specializes in the project (the only person who is aware of the grouping).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees Of Kermanshah University Of Medical Sciences

Street address

Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd., Kermanshah

City

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Province

Kermanshah

Postal code

6714673159

Approval date

2021-06-29, 1400/04/08

Ethics committee reference number

IR.KUMS.REC.1400.258

Health conditions studied

1

Description of health condition studied

Retinopathy of prematurity

ICD-10 code

H35.1

ICD-10 code description

Retinopathy of prematurity

Primary outcomes

1

Description

stage of retinopathy

Timepoint

Day 28 after birth and then every 1 to 2 weeks until the retinal vascular are complete

Method of measurement

Ophthalmoscopic eye examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the study group, after diagnosis of grade 1 or 2 retinopathy of prematurity in ophthalmic

examination, oral propranolol (Hakim Pharmaceutical Company - Made in Iran) is started at a dose of 0.5 mg / kg every 8 hours and the drug is continued until the retinal vascularity are complete (for at least 3 months) or the need for laser therapy .

Category

Prevention

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

Neonatal Intensive Care Unit of Imam Reza Hospital, Kermanshah

Full name of responsible person

Homa Babaei

Street address

Imam Reza Hospital, Parastar Boulevard , Kermanshah

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah 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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Pourang Mohammadi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Professor

Latest degree

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Other areas of specialty/work

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Phone**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