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 ophtalmic 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 Secinces

Country
Iran (Islamic Republic of)

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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 Committtees Of Kermanshah University Of Medical Sciences

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

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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 ophtalmic

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

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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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Professor

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Pediatrics

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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