Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Effect of oral propranolol in retinopathy of prematurity

Protocol summary

Study aim
The Effect of Oral Propranolol Treatment on Preterm Retinopathy

Design
A clinical trial with a control and case group, single-blind, randomized

Settings and conduct
This study was performed at the NICU of Shahid Sadoughi hospital in Yazd.the case group received 0.5 mg/kg/dose oral of propranolol every 12 hours. The retinopathy process in neonates of both groups was monitored every week until the final status of ROP was determined by retinal fixation without knowledge of the neonates of each group .

Participants/Inclusion and exclusion criteria
The study included preterm infants who had been admitted to NICU.twenty-seven newborns were included based on the following criteria: infants born with > 26 weeks' gestation ; birth weight < 1500 g; and retinopathy Grade I and II.The exclusion criteria were that the gestational age of< 26 weeks, Intra-ventricular hemorrhage (IVH) Grade II and III, neonates with congenital anomalies, Heart disease except Patent Ductus Arteriosus (PAD) , congenital infectious (TORCH) and acute sepsis.

Intervention groups
infants were randomly assigned to two group.the control group, does not receive any drug.In the case group, the initial dose of oral propranolol was 0.25 mg/kg/dose for 2 days. Then received to 0.5 mg/kg body weight/dose every 12 h.

Main outcome variables
Improvement in retinopathy, need for laser therapy, the need for injection of Bevacizumab, Complications of propranolol in the intervention group, hemodynamic variables before and 24 hours after the start of treatment in the case group, duration of drug in the intervention group according to the response to treatment

General information

Reason for update

Acronym
ROP

IRCT registration information
IRCT registration number: **IRCT20100520003982N1**
Registration date: **2019-01-23, 1397/11/03**
Registration timing: **retrospective**

Last update: **2019-01-23, 1397/11/03**
Update count: **0**

Registration date
2019-01-23, 1397/11/03

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
09131584474

Email address
dr.akrammirjalili@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-07-07, 1396/04/16

Expected recruitment end date
2018-07-07, 1397/04/16

Actual recruitment start date
2017-07-07, 1396/04/16

Actual recruitment end date
2018-11-04, 1397/08/13

Trial completion date
2018-12-21, 1397/09/30

Scientific title
Effect of oral propranolol in retinopathy of prematurity

Public title
Effect of propranolol in retinopathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm infants less than 1500 gr Preterm infants with gestational age greater than 26 weeks and less than 32 weeks Preterm infants with retinopathy grade I and II ROP Preterm infants admitted to NICU.
Exclusion criteria:
Congenital malformation cardiovascular problems except Patent Ductus Arteriosus (PAD) active sepsis Congenital infections (TORCH) Intraventricular hemorrhage (IVH) Grade II and III
Age
From **182 days** old to **224 days** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **27**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using a random number table . To use the random numbers table, we considered the table numbers from the left to read the table numbers. Then, by placing a number and moving in the left direction, the odd numbers for control and the pair numbers were considered for intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
The doctor examines newborns without knowing the grouping of them . Also, the Data analyzer did not know the groups and identified them as groups A and B.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Alam Square,Safayeh
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2017-07-07, 1396/04/16
Ethics committee reference number
IR-MEDICIN.REG.1396.48

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
Retinopathy process
Timepoint
On the 28th day after birth (before entering the study), every week until the end of study
Method of measurement
Indirect ophthalmoscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral propranolol (prilol 10 from OLIDARU): Start with dose of 0.25 mg / kg / dday for two days , then take 0.5mg / kg / day every 12 hours until the patient needs laser therapy or intra-ocular injection, or healing is complete without an aggressive treatment.
Category
Treatment - Drugs

2

Description
Control group: does not receive any drugs. Ophthalmic examinations (indirect ophthalmoscopy) were performed on a weekly basis from day 28 of birth for all infants admitted to the neonatal intensive care unit.In the absence of improvement in the baby, aggressive

therapies including laser therapy and Bevacizumab injections were performed.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Neonatal Neonatal Intensive Care Unit - Shahid Sadoughi Hospital, Yazd

Full name of responsible person
Dr. Mahmood Noori Shadkam

Street address
Shahid Sadughi Huspital, Sina rd, Shahid Ghandi Buval

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Akrm Mirjalili

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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
Yazd 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Akram Mirjalili

Position
Specialist Non-Faculty

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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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