Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

The efficacy of oral Propranolol in the treatment of the retinopathy of prematurity

Protocol summary

Study aim
Determination of the efficacy of oral propranolol in the management of retinopathy of prematurity

Design
Two arm parallel group double blind randomized trial with drug intervention and outcome assessment

Settings and conduct
Preterm infants admitted in Al Zahra's neonatal intensive care unit , have eye examination at 4-6 weeks after birth. Infants with the diagnosis of retinopathy of prematurity randomly allocate in two groups(oral propranolol or control group). All neonates will assess for need to laser therapy or Avastin administration at 38 weeks corrected gestation age and they will follow till eye examination is completed. A nurse that doesn't know patient's groups, will record their data.

Participants/Inclusion and exclusion criteria
Inclusion criteria: preterm infants with gestational age less than 32 weeks and birth weight less than 1250, Stage 1 , 2 for retinopathy of prematurity. Exclusion criteria: cardiovascular diseases, eye anomalies, acute renal failure, intraventricular hemorrhage

Intervention groups
After determination of retinopathy of prematurity in eye examination, infants in intervention group receive oral propranolol 0.5 mg/kg every 8 hours. Drug continues till complete vascularization of retina in eye examination or performing laser therapy. Infants in control group receive routine care for preterm infants without any drug for retinopathy of prematurity

Main outcome variables
Need to intervention (laser therapy or Avastin administration)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100512003915N21**
Registration date: **2018-11-12, 1397/08/21**
Registration timing: **retrospective**

Last update: **2018-11-12, 1397/08/21**
Update count: **0**

Registration date
2018-11-12, 1397/08/21

Registrant information

Name
Manizheh Mostafa Gharehbaghi

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-23, 1397/02/03

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of oral Propranolol in the treatment of the retinopathy of prematurity

Public title

Oral propranolol and retinopathy of prematurity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm infants with gestational age of less than 30 weeks Birth weight less than 1250 grams Stage 1 or 2 for retinopathy of prematurity

Exclusion criteria:

Infants with congenital anomalies Congenital or acquired cardiovascular disease in neonate Acute renal failure Severe intra-ventricular hemorrhage

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Seventy two preterm infants who met inclusion criteria and the diagnosis of retinopathy of prematurity confirms by ophthalmologist in eye examination, will randomly allocate in control and intervention groups by random numbers generated by random number generator. Ophthalmologist that performs eye examination and a nurse who records patients data are blind about patients groups and their received drugs.

Blinding (investigator's opinion)

Double blinded

Blinding description

Eye examiner ophthalmologist is not involved in medical management of neonates and isn't aware about patients received drugs. patients allocate to groups with respect to propranolol with coding and the nurse who records patients' data is blind to their groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Central University Building, Golghasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5168636883

Approval date

2018-04-23, 1397/02/03

Ethics committee reference number

IR.TBZMED.REC.1397.101

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

The need to intervention (laser therapy or Avastin administration) in retinopathy of prematurity

Timepoint

Corrected gestational age 38 weeks (gestational age plus age after birth in weeks)

Method of measurement

Ophthalmoscopic eye examination and performing laser therapy or Avastin administration

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We start treatment with oral propranolol (Osve, Iran) 0.5 mg/kg every 8 hr after detection of retinopathy of prematurity in first eye examination. Drug administration will continue till corrected gestational age of 38 weeks.

Category

Treatment - Drugs

2

Description

Control group receive routine care for preterm infants.

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU. Alzahra hospital
Full name of responsible person
Mina Hosseini
Street address
NICU, Al Zahra Hospital, South Artesh St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mina Hosseini
Position
fellowship of neonatology
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Person responsible for updating data

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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
There is no further information
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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