Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The comparison between Efficacy of Treatment With Propranolol in Newborns With Retinopathy of Prematurity and control

Protocol summary

Summary

The aim of this study is to comparie between Efficacy of Treatment With Propranolol in Newborns With Retinopathy of Prematurity and control. This is a Randomized Double blind Clinical Trial which will be conducted on 50 Premature patients (aged 23-31 weeks) with the diagnosis of Retinopathy of Prematurity. Children with the diagnosis of Retinopathey Prematurity and lack of diseases such as any type of heart disease, low blood pressure, brain hemmorhage included in this study. Patients with severe complications of propranolol such as severe bradycardy or low blood pressure excluded. The Premature Neonates were assigned to A& B groups based on Random Blockings. Group A recieved oral Propranolol (2 mg/kg/day divided in 4 doses for 26-31 weeks and 1mg/kg/day divided in 4 doses for 23-25 weeks) plus routine treatment and Group B recieved only routine treatment based on Ophtalmologist recommendation. Infants will be assessed until final vascularization for each 2 weeks and the level of Retinopathyand the Success of Treatment will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102524681N1**
Registration date: **2015-11-13, 1394/08/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

Name

Reza Sharafi

Name of organization / entity

Guilan University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 13 3336 9002

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Recruitment status

Recruitment complete

Funding source

The Vice Chancellor of Research of Guilan University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between Efficacy of Treatment With Propranolol in Newborns With Retinopathy of Prematurity and control

Public title

The comparison between Efficacy of Treatment With Propranolol in Newborns With Retinopathy of Prematurity and control

Purpose

Prevention

Inclusion/Exclusion criteria

Children with the diagnosis of retinopathy prematurity and lack of diseases such as any type of heart disease; low blood pressure; brain hemmorhage included in this

study. Patients with severe complications of propranolol such as severe bradycardy or low blood pressure excluded.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Guilan University of Medical Sciences

Street address
Guilan University of Medical Sciences, Namjoo Street

City
Rasht

Postal code

Approval date
2015-10-06, 1394/07/14

Ethics committee reference number
IR.GUMS.REC.1394.288

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
Grade of retinopathy

Timepoint
Each 2 weeks upto complete vascularization

Method of measurement
Grade of retinopathy 1-5

Secondary outcomes

empty

Intervention groups

1

Description
oral Propranolol (2 mg/kg/day divided in 4 doses for 26-31 weeks and 1mg/kg/day divided in 4 doses for 23-25 weeks) plus routine treatment

Category
Prevention

2

Description
outine treatment based on Ophtalmologist recommendation

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Dr Reza Sharafi

Street address
Namjoo Street

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person
Dr Abtin Heidarzadeh

Street address
Guilan University of Medical Sciences, Gaz Square

City
Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty