

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 compare 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 Retinopathy Prematurity and lack of diseases such as any type of heart disease, low blood pressure, brain hemorrhage included in this study. Patients with severe complications of propranolol such as severe bradycardia or low blood pressure excluded. The Premature Neonates were assigned to A& B groups based on Random Blockings. Group A received 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 received only routine treatment based on Ophthalmologist recommendation. Infants will be assessed until final vascularization for each 2 weeks and the level of Retinopathy and 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)

Phone

+98 13 3336 9002

Email address

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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 hemorrhage included in this

study. Patients with severe complications of propranolol such as severe bradycardia 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

Name of organization / entity

Guilan University of Medical Science

Full name of responsible person

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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