

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of near confluent laser versus combination of less dense laser and bevacizumab on prethreshold Retinopathy of prematurity (ROP) type 1 zone 2: Randomized clinical trial

Protocol summary

Study aim

To compare the rate of progression and re-treatment between two methods

Design

Two arm parallel group , double blinded randomized clinical trial on 43 patients using randomization chart

Settings and conduct

1- ROP clinic in Poostchi Eye Institute in Shiraz (the place of study accomplished) 2- type1 prethreshold ROP (sample population) 3- prospective double blinded randomized clinical trial using randomization chart (kind and way of making blind)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonates with retinopathy of prematurity; type 1 prethreshold, zone 2 location.
Exclusion criteria: Threshold Retinopathy of prematurity(ROP) ; ROP stage 4-5; vitreous hemorrhage; neovascularization of iris; aggressive posterior ROP; elevated ridge

Intervention groups

Intervantion group: less dense laser and intravitreal bevacizumab injection control group: Dense laser photocoagulation

Main outcome variables

Rate of vascularization progression; Rate of re-treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201120049450N1**

Registration date: **2021-12-27, 1400/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-27, 1400/10/06**

Update count: **0**

Registration date

2021-12-27, 1400/10/06

Registrant information

Name

Ehsan Namvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 4088

Email address

namvar_e@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-04, 1400/08/13

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of near confluent laser versus combination of less dense laser and bevacizumab on prethreshold Retinopathy of prematurity (ROP) type 1 zone 2: Randomized clinical trial

Public title

Combined laser and bevacizumab in ROP treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Retinopathy of prematurity Type 1 prethreshold location: Zone 2 of retina (from posterior circle to nasal ora serrata)

Exclusion criteria:

elevated demarcation ridge vitreous hemorrhage threshold zone 1 neovascularization of iris

Age

From **1 month** old to **4 months** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients included in the study were divided into patient and control groups based on a random number table. The table of random numbers starts from number 1 and is in the form of sequences that for example put number 1 as A and number 2 as A, number 3 to number 8 as B and ... This is a global standard table where group A can be considered a case and group B can be considered a control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Ophthalmologist team (those who exam and follow the neonates) are unaware of the group of patients

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Poostchi street, Poostchi eye clinic

City

Shiraz

Province

Fars

Postal code

7193616641

Approval date

2021-11-04, 1400/08/13

Ethics committee reference number

IR.SUMS.REC.1399.1302

Health conditions studied**1****Description of health condition studied**

Retinopathy of prematurity

ICD-10 code

H35.109

ICD-10 code description

Retinopathy of prematurity, unspecified, unspecified eye

Primary outcomes**1****Description**

Regression and progression of vascularization

Timepoint

Monthly up to 6 months

Method of measurement

Fundus examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: combined less dense laser and intravitreal Bevacizumab(dosage: 0.625micro). This combination treatment is performed in Khalili's operating room with prior reservation from the NICU. The next day after the operation, the baby is examined and then weekly for up to 4 weeks and the last examination after 24 weeks. At each stage, the stage of the disease is measured, and in case of regression of the stage and reduction of abnormal arteries, no new intervention is needed.

Category

Treatment - Drugs

2**Description**

Control group: dense laser treatment. This treatment is performed in Khalili's operating room with prior reservation from the NICU. The next day after the operation, the baby is examined and then weekly for up to 4 weeks and the last examination after 24 weeks. At each stage, the stage of the disease is measured, and in case of regression of the stage and reduction of abnormal arteries, no new intervention is needed.

Category

Treatment - Other

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Poostchi eye clinic

Full name of responsible person

Ehsan Namvar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Namvar and Mohammadhosein Norouzzadeh

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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

Shiraz 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Namvar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

Title and more details about the data/document

Outcomes of near confluent laser versus combined less dense laser and bevacizumab treatment of prethreshold ROP type 1 zone 2: Randomized clinical trial

When the data will become available and for how long

2021

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

If poostchi-eye research center permitted

From where data/document is obtainable

poostchi-eye research center

What processes are involved for a request to access data/document

request from poostchi-eye research center

Comments