

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the Inhibitory Effect of Phosphodiesterase Inhibitors Type 5 on the Development of Retinopathy of Prematurity in Preterm Infants

Protocol summary

Summary

Retinopathy of Prematurity (ROP) is a proliferative retinopathy, which involve the retina of premature infants. ROP is continues as a significant cause of blindness in premature infants. Low gestational age and exposure of premature newborns to high concentration of oxygen are the most significant risk factors in development of ROP. Exposure of immature retina to hyperoxia down regulates retinal vascular endothelial growth factor (VEGF). Retinal blood vessels constrict and may be obliterated, resulting in phase 1 ROP. In this randomized double blind clinical trial study we assess the effect of phoshodiesterase inhibitors type 5 via increasing of VEGF on development of phase 1 ROP as primary outcome and phase 2- 5 ROP; duration of Nasal Continuous Positive Airway Pressure (NCPAP), Mechanical Ventilation (MV)and oxygen therapy as secondary outcome in premature infants with gestational age of less than 32 weeks. Inclusion criteria: newborns with gestational age less than 32 weeks; need to oxygen therapy. Exclusion criteria: blood sugar \geq 150mg% more than 7 days; metabolic acidosis (pH< 7.2) more than 24h; blood transfusion greater than 10ml/kg in first 4 weeks of life; sepsis with fungi. NCPAP therapy with 4-6 cm H₂o begin as soon as possible in included cases. Infants who require Fio₂ \geq 40% to maintain o₂ saturation \geq 90% will be intubated and treated with intratracheal surfactant according to Intubation-Surfactant- Raid Extubation(INSURE) method. Mechanical ventilation was considered in babies with INSURE failure. Sildenafil or placebo will be administered to eligible cases till discontinue of supplemental oxygen. Development of Retinopathy was assessed .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102314215N3**

Registration date: **2016-02-17, 1394/11/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-17, 1394/11/28

Registrant information

Name

Masoud Dehdashtian

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1221 6503

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Inhibitory Effect of Phosphodiesterase Inhibitors Type 5 on the Development of Retinopathy of Prematurity in Preterm Infants

Public title

Effect of Sildenafil on the Development of Retinopathy of Prematurity in Preterm Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: newborns with gestational age less than 32 weeks; need to oxygen therapy. Exclusion criteria: blood sugar $\geq 150\text{mg}\%$ more than 7 days; metabolic acidosis ($\text{pH} < 7.2$) more than 24h; blood transfusion greater than 10ml/kg in first 4 weeks of life; sepsis with fungi.

Age

From **1 day** old to **3 months** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic Comite of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code**Approval date**

2015-02-28, 1393/12/09

Ethics committee reference number

AJUMS.REC.1393.405

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

Vision Disorder

ICD-10 code

H35.1

ICD-10 code description

Retinopathy of prematurity Retrolental fibroplasia

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

Retinopathy stage 1

Timepoint

at 32 postconceptual age till 45 weeks postconceptual age

Method of measurement

Retinoscopy

Secondary outcomes**1****Description**

stage2-5 retinopathy

Timepoint

at 32 till 45 weeks postconceptual age

Method of measurement

Retinoscopy

2**Description**

The period of NCPAP therapy

Timepoint

Hour

Method of measurement

Use of NCPAP

3**Description**

Period of Mechanical Ventilation therapy

Timepoint

Hour

Method of measurement

Use of ventilator

4**Description**

Period of oxygen therapy

Timepoint

Hour

Method of measurement

Use of oxygen

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

In intervention group NCPAP therapy with 4-6 cm H₂O

begin as soon as possible in included cases. Infants who require $F_{iO_2} \geq 40\%$ to maintain o_2 saturation $\geq 90\%$ will be intubated and treated with intratracheal surfactant according to Intubation- Surfactant- Raid Extubation(INSURE) method. Mechanical ventilation was considered in babies with INSURE failure. Sildenafil 1 mg/kg q8hr will be administered to eligible cases till discontinue of supplemental oxygen.

Category

Treatment - Drugs

2**Description**

In control group NCPAP therapy with 4-6 cm H₂O begin as soon as possible in included cases. Infants who require $F_{iO_2} \geq 40\%$ to maintain o_2 saturation $\geq 90\%$ will be intubated and treated with intratracheal surfactant according to Intubation- Surfactant- Raid Extubation(INSURE) method. Mechanical ventilation was considered in babies with INSURE failure. placebo with equal color and volume will be administered to eligible cases till discontinue of supplemental oxygen.

Category

Treatment - Drugs

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

Imam Khomeini Hospital

Full name of responsible person

Masoud Dehdashtian

Street address

Azadegan st. Imam Khomeini Hospital, Ahvaz, Khozestan Province, IRAN

City

Ahvaz

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

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ghadiri Ataollah

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Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Khozestan province, IRAN

City

Ahvaz

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, Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Masoud Dehdashtian

Position

Neonatologist

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Position

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Web page address

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