Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Inhibitory Effect of Phosphodisterase 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≥ 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≥ 40% to maintain o2 saturation≥ 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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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 Phosphodisterase 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≥ 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.
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 Fio2≥ 40% to maintain o2 saturation≥ 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 Fio2≥ 40% to maintain o2 saturation≥ 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

Street address

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

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Position
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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