Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Prevention of Blindness in Retinopathy of Prematurity by Intravitreal Injection of Bevacizumab

Protocol summary

Summary

This study aims to evaluate the outcome and prognostic factors of the intravitreal administration of bevacizumab monotherapy for retinopathy of prematurity (ROP), as emerged from our experience. This is a retrospective case series that was carried out at the "Iuliu Hatieganu" University of Medicine and Pharmacy from Cluj-Napoca, Romania. It includes all the consecutive infants who received intravitreal bevacizumab monotherapy for ROP, from January 1st 2009 throughout July 31st 2013. The statistical analysis was performed with the program SPSS 20.0.0 (Chicago, Illinois, USA).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101618966N2**
Registration date: **2014-10-23, 1393/08/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-23, 1393/08/01

Registrant information

Name
Simona Delia Nicoara
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

This study did not receive any monetary or material suppport.

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-07-31, 1392/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Prevention of Blindness in Retinopathy of Prematurity by Intravitreal Injection of Bevacizumab

Public title

The treatment of retinopathy of prematurity with Avastin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all the premature new borns that received intravitreal bevacizumab injections for retinopathy of prematurity

Age

From **20 days** old to **3 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the "Iuliu Hatieganu" University of Medicine and Pharmacy
Street address
8, V. Babes str.
City
Cluj-Napoca
Postal code
400012
Approval date
2011-12-12, 1390/09/21
Ethics committee reference number
466

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
regression of retinopathy of prematurity
Timepoint
one week after the intravitreal injection of bevacizumab
Method of measurement
indirect ophthalmoscopy

Secondary outcomes

1

Description
condition of the retina
Timepoint
52 weeks after the intravitreal injection of bevacizumab
weeks
Method of measurement
indirect ophthalmocsopy

Intervention groups

1

Description
A dose of bevacizumab of 0.625 mg in 0.025 ml was injected in each eye from the study sample, according to the following protocol: The pupils were dilated with a mixture of tropicamide 0.5% and phenylephrine 0.5%. Anesthesia was achieved with 0.5% proparacaine hydrochloride administered topically, 3 times, every 2 minutes before the injection. Every eye was prepared in a sterile manner using 5% povidone iodine which was also instilled in the eye 3 minutes prior the injection. A nurse hold the infant's head during the procedure and 0.025 ml of bevacizumab (0.625 mg) were injected in pars plicata, 1.5 - 1.75 mm away from the limbus, with a 30 G needle, perpendicularly on the globe initially and then slightly directed toward the center of the eyeball. After the injection, the patients received topical tobramycin, 5 times/day, for 3 days. The patients were re-examined the next day and then every week to monitor the regression of the disease. The follow-up continued for 52 weeks, every 1 or 2 weeks until full vascularization of the retina was observed. Full vascularization was defined as follows: vascularization as far as it would develop without an active component or clinically significant tractional elements. All the treatments were carried out by the same physician and the examinations were performed by three ophthalmologists experienced in ROP.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
"Iuliu Hatieganu" University of Medicine and Pharmacy
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
No sponsor

Full name of responsible person
Not applicable
Street address
Not applicable
City
Not applicable
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
No sponsor
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

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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