

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Intravitreal Injection of Triamcinolone Acetonide in Retinitis Pigmentosa with cystoids macular edema

Protocol summary

Summary

The purpose of this study was to assess the response rate to intravitreal injection of Triamcinolone in cases of RP with CME. In this study, the patients with a definitive diagnosis of RP were assessed and those with a central foveal thickness less than 250 microns (according to OCT), and a history of glaucoma or cataract surgery were excluded. The sample was 87 patients with RP, among which, those with CME were selected and enrolled after they signed written informed consents. BCVA, fluorescein angiography, OCT, and autofluorescence were conducted at different time intervals after intravitreal injection of 4mg Triamcinolon, and results were compared to draw conclusions. The primary outcome measure was changes in visual acuity (BCVA) and the secondary outcome measure was the central foveal thickness as measured with OCT, and comparing the pre- to post-injection values.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104266293N1**
Registration date: **2011-06-24, 1390/04/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-24, 1390/04/03

Registrant information

Name

Mohammad Riazi Esfahani

Name of organization / entity

Eye Research Center, Farabi Eye Hospital

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2007-09-23, 1386/07/01

Expected recruitment end date

2008-04-19, 1387/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravitreal Injection of Triamcinolone Acetonide in Retinitis Pigmentosa with cystoids macular edema

Public title

Intravitreal Injection of Triamcinolone Acetonide in Retinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of RP based on paraclinic tests
Exclusion criteria: one-eyed patients, history of glaucoma, any opacity in media and history of intraocular surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: **161**

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
Tehran University Eye Research Center

Street address
Tehran, Farabi eye hospital

City
Tehran

Postal code

Approval date
2011-05-23, 1390/03/02

Ethics committee reference number
ERC/s/903

Health conditions studied

1

Description of health condition studied

cystoids macular edema (CME) secondary to retinitis pigmentosa (RP)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

visual acuity

Timepoint
3 weeks, 3 months and 6 months after the injection

Method of measurement
snellen chart

Secondary outcomes

1

Description

macular thickness and angiographic changes

Timepoint
3 weeks, 3 and 6 months after the injection

Method of measurement
Slit lamp examination, fundoscopy and OCT

Intervention groups

1

Description

Intravitreal injection of 4mg Triamcinolon in 0.1cc were done only once using a 29 gauge needle at 3.5mm posterior to the limbus. Complete eye examinations including best corrected visual acuity (BCVA) tests, photography with autofluorescence, fluorescein angiography, and OCT is done before the injection and at 1 month, 3 months, and 6 months after injection. Results were then was compared. In cases of bilateral CME, only one eye was selected for injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi Eye Hospital, Tehran University of Medical Sciences

Full name of responsible person
Dr Mohammad Riazi Esfahani

Street address
Farabi eye hospital, Qazvin Sq., South Kargar St, Tehran, Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Alireza Lashay

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Farabi eye hospital, Qazvin Sq., South Kargar St, Tehran, Iran

City
Tehran

Grant name
ندارد

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
vice-chancellor of Farabi eye hospital, TUMS
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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