Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Macular laser Photocoagulation with or without Intravitreal Injection of Bevacizumab (Avastin) or Triamcinolone Acetonide for Diffuse Diabetic Macular Edema

Protocol summary

Summary

Background: Diabetic maculopathy is an important cause of visual loss around the world. Gold standard treatment of diabetic maculopathy is macular grid laser photocoagulation, but less than 3% of patients gain better visual acuity after this treatment. Because there is not an effective treatment for diabetic maculopathy, it is needed to use another therapy with laser photocoagulation to treat diabetic macular edema. Purpose: In this study we evaluate the effect of macular laser photocoagulation on vision and macular thickness of patients of macular edema alone and with intra vitreral injection of triamcinolone or bevacizumab. Method: 105 patients were randomized in three group; first group, grid laser photocoagulation , second group, 1 week after Macular Laser Photocoagulation 4 mg Tramcinolone Acetonide will inject Intravitrealy and third group, 1 week after Macular Laser Photocoagulation,1.25mg Bevacizumab(Avastin) will inject intravitrealy. In all patients visual acuity and macular thickness measured before and 3 months after treatment and compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205029617N1**
Registration date: **2012-05-10, 1391/02/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-05-10, 1391/02/21

Registrant information

Name

Behnam Sadeghi

Name of organization / entity

Jondishapur Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1222 8076

Email address

sadeghi.b@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice_chancellor in Research Affairrs of Ahvaz Jundishapur Univercity of Medical Sciences

Expected recruitment start date

2011-05-10, 1390/02/20

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Macular laser Photocoagulation with or without Intravitreal Injection of Bevacizumab (Avastin) or Triamcinolone Acetonide for Diffuse Diabetic Macular Edema

Public title

Efficacy of Macular laser Photocoagulation with or without Intravitreal Injection of Bevacizumab (Avastin) or Triamcinolone Acetonide for Diffuse Diabetic Macular Edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients of either gender aged more than18 years; diabetes mellitus (type 1 or 2); best corrected visual acuity (BCVA) in the study eye between 35 and 69 ETDRS letters at 4 m (Snellen equivalent 1/10-5/10); central foveal thickness more than 270 micrometer; media clarity, pupillary dilation, and subject cooperation sufficient for adequate fundus imaging; intraocular pressure (IOP)less than 21 mmHg; ability to return for regular study visits; fellow eye has vissual acuity more than 20/400; fellow eye has received no antivascular endothelial growth factor (VEGF) treatment within the past 3 months and diffuse diabetic macular edema based on fluorescein angiography. Exclusion criteria(ocular criteria were applied to the study eye only): macular ischemia (foveal avascular zone [FAZ] more than1000 micrometer or severe perifoveal intercapillary loss on fluorescein angiography); macular edema due to a cause other than diabetic maculopathy; coexistent ocular disease: a preexisting ocular condition that was likely to preclude vissual acuity improvement despite resolution of macular edema (foveal atrophy, amblyopia, retinal vascular occlusion, neovascular glaucoma, ...); proliferative diabetic retinopathy more than one disc in area in peripheral retina with or without vitreous hemorrhage and history of intraoccular surgery like as cataract sugery or vitrectomy.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

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

Ahvaz Jundishapur University of medical sciences

Street address

Central Department-Golestan Square

City

Ahvaz

Postal code

6135715794

Approval date

2011-05-08, 1390/02/18

Ethics committee reference number

ETH-139

Health conditions studied

1

Description of health condition studied

Diffuse Diabetic Macular Edema

ICD-10 code

H30-H36

ICD-10 code description

Disorders of choroid and retina

Primary outcomes

1

Description

Central Macular Thickness

Timepoint

Before and Three months after Treatment

Method of measurement

Central Macular Thickness Evaluate with OCT Instrument

2

Description

Visual Acuity

Timepoint

Before Treatment and Three Months after Treatment

Method of measurement

Visual Acuity check with snellen chart

Secondary outcomes

empty

Intervention groups

1

Description

In group of Laser Photocoagulation alone, we do Macalar Laser Photocoagulation .

Category

Rehabilitation

2

Description

In group of Laser Photocoagulation with intravitreal injection of Triamcinolone Acetonide, we do Macular Laser Photocoagulation then 4mg Triamcinolone Acetonde will inject intravitrealy one week later.

Category
Treatment - Drugs

3

Description
In group of Laser Photocoagulation with intravitreal Bevacizumab(Avastin), we do Macular laser photocoagulation then 1.25mg Bevacizumab will inject intravitrealy one week later.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hospital-Ahvaz
Full name of responsible person
Dr.Sadeghi.Behnam
Street address
Ophthalmology Department-Emam Hospital-Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor in Research Affairs Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Feghhi.Mostafa
Street address
Golestan Square-Ahvaz
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 in Research Affairs 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 Univercity of Medical Scieces
Full name of responsible person
Dr.Sadeghi.Behnam
Position
Resident of Ophthalmology
Other areas of specialty/work
Street address
Department of Ophthalmology-Emam Hospital-Ahvaz
City
Ahvaz
Postal code
6135715794
Phone
+98 61 1222 8076
Fax
+98 61 1222 8076
Email
sadeghi.b@ajums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Kasiri.Ali
Position
Attending of Ophthalmology-Vitreoretinal Surgen
Other areas of specialty/work
Street address
Department of Ophthalmology-Emam hospital-Ahvaz
City
Ahvaz
Postal code
6135715794
Phone
+98 61 1222 2670
Fax
+98 61 1222 8076
Email
dr.pazyar@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Sadeghi.Behnam
Position
Resident of Ophthalmology
Other areas of specialty/work
Street address
Department of Ophthalmology-Emam Hospital-Ahvaz
City

Ahvaz
Postal code
613571594
Phone
+98 61 1222 8076
Fax
+98 61 1222 8076
Email
sadeghi.b@ajums.ac.ir
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