

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 vitreal 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 Intravitreally and third group, 1 week after Macular Laser Photocoagulation,1.25mg Bevacizumab(Avastin) will inject intravitreally. 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

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice_chancellor in Research Affairs of Ahvaz Jundishapur University 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 than 18 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 visual acuity more than 20/400; fellow eye has received no anti-vascular 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 than 1000 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 visual 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 intraocular surgery like as cataract surgery 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

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Central Department-Golestan Square
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Ahvaz
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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 Macular 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 Acetonide will inject intravitreally 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 intravitreally one week later.

Category

Treatment - Drugs

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

Emam Hospital-Ahvaz

Full name of responsible person

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

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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**

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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