

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intravitreal autologous plasmin injection, in treatment of diffuse diabetic macular edema

Protocol summary

Summary

Enzymatic vitreolysis by plasmin injection, is the newest method of treatment, inducing posterior Vitreous detachment, by its enzymatic action, that affects on laminin and fibronectin, located between posterior vitreous, and internal limiting membrane, and releases the traction of posterior cortex, which plays a major role in the increase, and chronification of macular edema, and finally aids in edema resolution, Specially if there is some evidence of diffuse diabetic macular edema or, posterior hyaloid traction. In this study we will try to evaluate the effect of autolog plasmin injection produced by urokinase, without vitrectomy, as a primary treatment of diffuse diabetic macular edema. Inclusion criteria contain diabetic patients, which suffer from diffuse diabetic macular edema. Exclusion criteria contain uncontrolled hypertension, unstable blood sugar level, renal failure, history of ocular hypertension, glaucoma, ischemic macular or peripheral retina, history of ocular surgery in the last 6month, posterior vitreous detachment, and proliferative diabetic retinopathy. Study will be performed by one time injection of intravitreal plasmin in case group, without any intervention in control group, in totally 20 eyes with diffuse diabetic macular edema, and the effect on macular edema will evaluate by measurement of the changes in visual acuity and central macular thickness before, 1 month, and 2 month after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050522112N1**

Registration date: **2015-06-17, 1394/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-17, 1394/03/27

Registrant information

Name

Ali Hamidian Shoormasti

Name of organization / entity

Alzahra Eye Hospital, Zahedan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Zahedan University of Medical Science

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravitreal autologous plasmin injection, in treatment of diffuse diabetic macular edema

Public title

Effect of intraocular plasmin injection, in diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients suffer from diffuse diabetic macular edema. Exclusion criteria: Uncontrolled hypertension; Unstable blood sugar level; Renal failure; History of Ocular hypertension and, Glaucoma; Ischemic macular or peripheral Retina; History of ocular surgery in last 6 month; Posterior vitreous detachment; Proliferative diabetic retinopathy.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences, ethics committee

Street address

University of Medical sciences, Khalij fars Blv, Dr. Hessabi Sqhare, Zahedan, Iran

City

Zahedan

Postal code

98167-43463

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

1240

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

H35.0

ICD-10 code description

Background retinopathy and retinal vascular changes

Primary outcomes

1

Description

Central macular thickness

Timepoint

Before intervention, 1month, and 2 month later

Method of measurement

Ocular coherent tomography.

2

Description

Visual acuity

Timepoint

Before intervention, 1month, and 2month later

Method of measurement

Snellen chart

Secondary outcomes

empty

Intervention groups

1

Description

One time injection of autologous serum plasmin, 0.2 ml intravitreal

Category

Treatment - Drugs

2

Description

Without any intervention, in control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Eye Hospital, Zahedan

Full name of responsible person

Dr. Ali Hamidian Shoormasti

Street address

No15, Hashemian Alley, 3rd Neyestan Street, Pasdaran Ave, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Zahedan University of Medical Science

Full name of responsible person

Dr. Montazeri far

Street address

University of Medical Science, Khalij Fars Blvd, Dr. Hesabi Square, Zahedan, Iran

City

Zahedan

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 of Zahedan University of Medical Science

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**

Alzahra Eye Hospital, Zahedan

Full name of responsible person

Dr. Ali Hamidian Shoormasti

Position

Ophthalmology resident

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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