

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of safety and efficacy of intravitreal injection of recombinant Tissue Plasminogen Activator before vitrectomy for diabetic Tractional Retinal Detachment on facility and outcome of surgery

Protocol summary

Study aim

Evaluation of recombinant Tissue Plasminogen Activator efficacy on facility of vitrectomy for diabetic Tractional Retinal Detachment

Design

A randomized, blinded, sham controlled clinical trial with a parallel group design of 38 patients

Settings and conduct

In this prospective, double blinded randomized control trial, subjects with diabetic tractional retinal detachment who are candidate for vitrectomy will be enrolled in Rasoul Akram hospital. The subjects will be randomized into 50 micrograms/0.1 ml intravitreal tissue plasminogen activator inhibitor and intravitreal bevacizumab or sham injection and intravitreal bevacizumab, 5 to 9 days prior to surgery. anatomical success rate will be evaluated 3 months after surgery in both groups.

Participants/Inclusion and exclusion criteria

Subjects with diabetic tractional retinal detachment who are candidates for vitrectomy will be enrolled

Intervention groups

Intervention group: 19 eyes of 19 patients will receive intravitreal injections of bevacizumab (2.5 mg/0.1cc) and recombinant tPA (50 µg/0.1cc) at one session, 5-9 days prior to vitrectomy. Control group: 19 eyes of 19 patients will receive intravitreal injection of bevacizumab (2.5 mg/0.1cc) and sham injection at one session, 5-9 days prior to vitrectomy

Main outcome variables

Post surgical anatomical success rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046522N1**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Khalil Ghasemi Falavarjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 8811

Email address

ghasemifalavarjani.k@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of intravitreal injection of recombinant Tissue Plasminogen Activator before vitrectomy for diabetic Tractional Retinal Detachment on

facility and outcome of surgery

Public title

Evaluation of efficacy of recombinant Tissue Plasminogen Activator on facility of vitrectomy for diabetic Tractional Retinal Detachment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic Tractional Retinal Detachment Candidated for vitrectomy

Exclusion criteria:

combined tractional-rhegmatogenous retinal detachment
significant media opacity

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization using random numeric table

Blinding (investigator's opinion)

Double blinded

Blinding description

Simple randomization using random numeric table

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-12-04, 1398/09/13

Ethics committee reference number

IR.IUMS.FMD.REC.1398.386

Health conditions studied

1

Description of health condition studied

Diabetic Tractional Retinal Detachment

ICD-10 code

E11.3522

ICD-10 code description

Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula

Primary outcomes

1

Description

anatomical success rate

Timepoint

before surgery, one month and three months after surgery

Method of measurement

clinical examination

Secondary outcomes

1

Description

surgical facility

Timepoint

conclusion of surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 19 eyes of 19 patients received intravitreal injections of bevacizumab (2.5 mg/0.1cc) and recombinant tPA (50 µg/0.1cc) at one session, 5-9 days before vitrectomy

Category

Treatment - Drugs

2

Description

Control group: 19 eyes of 19 patients received intravitreal injection of bevacizumab (2.5 mg/0.1cc) and sham injection at one session, 5-9 days before vitrectomy

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Eye Clinic of Rassoul Akram Hospital

Full name of responsible person

Esrafil Shad

Street address

Rasoul Akram Hospital, Niyayesh Ave., Sattarkhan Ave, 8th fl.

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Khalil Ghasemi Falavarjani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available