

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The Comparison of the Efficacy of Intravitreal Injection of Iranian Made Ranibizumab (Vicentis®) with Imported Ranibizumab (Lucentis®) in Patients with Diabetic Macular Edema: A phase III, Two-armed, Double-blind, Parallel, Active-controlled, and Noninferiority Clinical Randomized Trial

Protocol summary

Study aim

The Comparison of the Safety and Efficacy of Intravitreal Injection of Vicentis® with Lucentis® in Patients with Diabetic Macular Edema

Design

A phase III, two-armed, double-blind, parallel, active-controlled, and non-inferiority clinical randomized trial; Randomization method: Block, Individual, by use of web-based software; Sample size: 154

Settings and conduct

154 patients with diabetes mellitus referring to Rassoul Akram hospital eye clinic will be included in the study. Patients will be randomized into one of the following groups: Ranibizumab (Vicentis) or Ranibizumab (Lucentis). Both drugs are indistinguishable for patients and the medical staff, and the only informed person is the nurse who is responsible for preparing the Ranibizumab. Additionally, people who evaluate the results and analyze data are not aware of the patients' group assignments. After intravitreal injection of ranibizumab, the variables will be evaluated at intervals of 1 month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 80 years old; Diabetes mellitus type 1 or 2; Center involving macular edema with a central subfield thickness of >300; Early treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity letter score of 24 to 78 (20/32 to 20/400); Signed written informed consent; Exclusion criteria: History of intravitreal injection within 2 months ago, ocular surgery, glaucoma or ocular hypertension; Any media opacity; Monocular patients; Proliferative diabetic retinopathy with high-risk characteristics; HbA1c>10%; Use of IOP-lowering drops, systemic

corticosteroids or nonsteroidal anti-inflammatory eye drops

Intervention groups

Intervention group: An intravitreal injection of 0.05 ml Ranibizumab (Aracell zist daru); Control group: An intravitreal injection of 0.05 ml Ranibizumab (Roche)

Main outcome variables

Central macular thickness

General information

Reason for update

To update the protocol and address the new site of patients recruitment

Acronym

SVLD

IRCT registration information

IRCT registration number: **IRCT20170303032845N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **prospective**

Last update: **2021-01-19, 1399/10/30**

Update count: **1**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

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Name of organization / entity

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Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2019-12-22, 1398/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Efficacy of Intravitreal Injection of Iranian Made Ranibizumab (Vicentis®) with Imported Ranibizumab (Lucentis®) in Patients with Diabetic Macular Edema: A phase III, Two-armed, Double-blind, Parallel, Active-controlled, and Noninferiority Clinical Randomized Trial

Public title

The Comparison of Efficacy Between Iranian Made Ranibizumab and Imported Ranibizumab in Diabetic Patients with Macular Edema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetes mellitus type 1 or 2 Center involving macular edema with a central subfield thickness (CST) of >300 Early treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity letter score of 24 to 78 (20/32 to 20/400) HbA1c<9% Blood Pressure <150/100 Triglyceride and LDL up to 20% higher than upper normal limits Pseudophakic patients are allowed to enter the study. Signed written inform consent

Exclusion criteria:

History of intravitreal injection within the past 2 months History of any ocular surgery within the past 6 months History of glaucoma or ocular hypertension Any media opacity in the cornea, lens and vitreous body which interferes with eye examination and imaging. Monocular patients Pregnant or breastfeeding women Proliferative diabetic retinopathy (PDR) with high-risk characteristics HbA1c>10% Smoking (more than 10 cigarettes per day) Use of acetazolamide tablets or intraocular pressure-lowering drops Use of systemic corticosteroids or nonsteroidal anti-inflammatory eye drops (NSAIDs)

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

- Data analyser

Sample sizeTarget sample size: **154****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method: Block randomization Unit of Randomization: Individual Randomization tool: web-based software

<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)

Double blinded

Blinding description

Both Ranibizumab drugs are indistinguishable for patients and the medical staff, and the only informed person is the nurse who is responsible for preparing the Ranibizumab according to the physician's instructions. Since Ranibizumab route of administration is intravitreal injection, it is possible to blind patients to the treatment groups. Additionally, people who evaluate the results and analyze data are not aware of the patients' group assignments.

Placebo

Not 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

Iran University of Medical Sciences, Shahid Hemmat Highway.

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1449614535

Approval date

2019-01-08, 1397/10/18

Ethics committee reference number

IR.IUMS.REC.1397.806

2**Ethics committee****Name of ethics committee**

Farabi Eye Hospital- Tehran University of Medical Sciences

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The south Kargar St, Qazvin Square

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۱۳۳۶۶۱۶۳۵۱

Approval date

2020-12-29, 1399/10/09

Ethics committee reference number

IR.TUMS.FARABIH.REC.1399.033

Health conditions studied

1

Description of health condition studied

Diabetic retinopathy

ICD-10 code

E10.3

ICD-10 code description

Type 1 diabetes mellitus with ophthalmic complications

Primary outcomes

1

Description

Central macular thickness

Timepoint

At the beginning of the study (before the intervention),
30 days after injection

Method of measurement

Optical coherence tomography

Secondary outcomes

1

Description

Visual acuity

Timepoint

At the beginning of the study (before the intervention), 7
and 30 days after injection

Method of measurement

Snellen chart

Intervention groups

1

Description

Intervention group: An intravitreal injection of 0.05 ml
Ranibizumab (Aracell zist daru)

Category

Treatment - Drugs

2

Description

Control group: An intravitreal injection of 0.05 ml

Ranibizumab (Roche)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rassoul Akram hospital

Full name of responsible person

Sayyed Amirpooya Alemzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aracell zist daru

Full name of responsible person

Mohsen Nayebpour

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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
Aracell zist daru
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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

No - There is not 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