Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Saftey 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 (Visentis) 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

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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)
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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/lists
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
Street address

The south Kargar St, Qazvin Square
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Province
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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
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Sponsors / Funding sources

1

Sponsor
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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
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
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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