Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of therapeutic effect intravitreal injection of methotrexate in persistent diabetic macular edema

Protocol summary

Summary

Purpose: Evaluation of therapeutic of effect intravitreal injection of methotrexate in persistent diabetic macular edema Design: Prospective interventional(Clinical trial-Quasi experimental) participant:42 eyes with resistant diabetic macular edema will receive intraviteral methotrexate Duration: six month follow up study intervention: using of intra viteral injection of 400µg MTX in eyes with resistant diabetic macular edema ,BCVA ,central subfleid thickness and macular thickness will be recorded before and 1,3,and 6 months after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610098983N2**
Registration date: **2016-10-30, 1395/08/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

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Mohammad rasoul Sabouri
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect intravitreal injection of methotrexate in persistent diabetic macular edema

Public title

Intravitreal injection of methotrexate in persistent diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patient with central subfleid thickness (CST) More than 250 micrometers. 2. Best corrected visual acuity 20/ 200 and more. 3.lack of one line improvement, at least, in best corrected visual acuity or at least 10% reduction in central subfield thickness after intravitreal injection of three consecutive Bevacizumab and one injection co-administration bevacizumab -triamcinolone every 4-6week intervalor 3 consecutive Bevacizumab every 4 -6 weeks plus macular photouagulation. 4. Lack of traction on the macula, which is identified on clinical examination and OCT 5. Patient who agree entering the study (consent form) Exclusion criteria : 1. Any previous intraocular surgery that was done in more than 1year ago 2. Any laser photocuagulation treatment in the past 4 months . 3. Need to any intraocular surgery, intraocular injection or laser photocoagulation in the follow-up period . 4. Any

traction on the macula which is identified on clinical examination and OCT. 5. No control of blood pressure, blood sugar and blood lipid during study

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Consecutive nonrandomized prospective clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Guilan University of Medical Sciences

Street address
Guilan University of Medical Sciences

City
Rasht

Postal code

Approval date
2016-08-13, 1395/05/23

Ethics committee reference number
IR.GUMS.REC.1395.174

Health conditions studied

1

Description of health condition studied
Resistant macular edema in diabetic patients

ICD-10 code
H35.8

ICD-10 code description
Distrubtion of retinal layers due to edema

Primary outcomes

1

Description
Change in macular thickness

Timepoint
1, 3 and 6 months after injection

Method of measurement
OCT

Secondary outcomes

1

Description
Change in visual acuity

Timepoint
1, 3 and 6 months after injection

Method of measurement
Snellen chart

Intervention groups

1

Description
using of intra viteral injection of 400µg MTX in eyes with resistant diabetic macular edema ,BCVA ,central subfleid thickness and macular thickness will be recorded before and 1,3,and 6 months after injection.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital

Full name of responsible person
Dr Mohammad Rasoul Sabouri

Street address
Amiralmomenin Hospital, 17 Shahrivar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Sciences,Vice chancellor for research

Full name of responsible person
Mrs Susan Komaie

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Guilan University of Medical Sciences, 17 Shahrivar Street

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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
Guilan University of Medical Sciences,Vice chancellor for research
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

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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