

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

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

Protocol summary

Summary

Purpose: Evaluation of therapeutic 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 intravitreal methotrexate Duration: six month follow up study intervention: using of intra vitreal injection of 400µg MTX in eyes with resistant diabetic macular edema ,BCVA ,central subfield 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

Name

Mohammad rasoul Sabouri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 6886

Email address

sabouri@gums.ac.ir

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 subfield 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 photocoagulation. 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 photocoagulation 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 vitreal 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

City

Rasht

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

Street address

Guilan University of Medical Sciences, 17 Shahrivar Street

City

Rasht

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****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Mohammad rasoul Sabouri

Position

Assistant Professor

Other areas of specialty/work**Street address**

17 Shahrivar Street

City

Rasht

Postal code**Phone**

+98 13 3323 6886

Fax**Email**

r_sabouri2002@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Mohammad rasoul Sabouri

Position

Assistant Professor

Other areas of specialty/work**Street address**

17 Shahrivar Street

City

rasht

Postal code**Phone**

+98 13 3323 6886

Fax**Email**

sabouri2002@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Shila Kianmehr

Position

MSc

Other areas of specialty/work**Street address**

17 Shahrivar Street

City

Rasht

Postal code**Phone**

+98 13 3323 6886

Fax**Email**

shila.kianmehr@gmail.com

Web page address**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*