Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the impacts of Doxycycline and placebo added to intraocular Bevacizumab on required numbers of injection and therapeutic progress in patients suffering from exudative Age related Macular Degeneration.

Protocol summary

Summary

Objectives: According to anti-inflammatory effects of Tetracycline and pathophysiology of exudative Age related Macular Degeneration (AMD), the aim of this study is to compare the effect of Doxycycline added to intraocular Bevacizumab on required number of injections and clinical course in patients suffering from wet AMD. Design: This study is the first and the second phase of a randomized, double-blind, placebo-controlled, single-center clinical trial. Three hundred patients with subfoveal exudative AMD will be divided into intervention group (n = 200) and placebo control (n = 100) with Block Randomization (block size of 6, 9 and 12). Setting, conduct and Intervention: In addition to standard treatment by intraocular Bevacizumab based on treat and extent regimen, participants in the intervention group will receive a daily dose of 200 mg of Doxycycline in 2 divided doses. In intervention group, half of the patients will receive Doxycycline until the end of the induction phase while the other half will be treated for 4 months. In control group, patients will receive placebo twice a day for 4 months. Patients eligible for the study: patients who have exudative AMD and haven't received any other treatment, referred to Farabi hospital. Exclusion criteria: patients with history of systemic disease. Also patients with maximum lesion size of more than 2 Disk Diameters will be excluded. Main outcome variables: Participants will be evaluated for number of injections and induction time as well as foveal thickness, visual acuity, size of neovascularization and relapse of disease.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015020921017N1**
Registration date: **2017-09-06, 1396/06/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-06, 1396/06/15

Registrant information

Name

Pourya Azimi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the impacts of Doxycycline and placebo added to intraocular Bevacizumab on required numbers of injection and therapeutic progress in patients suffering from exudative Age related Macular Degeneration.

Public title
Co-management of exudative AMD with Avastin and Doxycycline
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: occult choroidal neovascularization (classic CNV); subfoveal age related macular degeneration; naïve patients; central retinal thickness plus subfoveal fluid ≤ 500 µm; lesion size ≤ 2 Disk Diameter; no history for neither systemic disease nor myocardial infarction Exclusion criteria: vitreomacular adhesion; fibrovascular scar; geographic atrophy; history of intraocular pressure rise.
Age
From **50 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
In this double blinded study, participants will be divided by Block Randomization (Block Size: 6,9,12) into intervention group (n = 200) and placebo control (n = 100).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
School of Medicine, Tehran University of Medical Sciences, Enghelab st., Tehran, Iran
City
Tehran
Postal code
1417613151
Approval date
2016-08-10, 1395/05/20
Ethics committee reference number
IR.TUMS.FARABIH.REC.1395.438

Health conditions studied

1

Description of health condition studied
wet Age related Macular Degeneration
ICD-10 code
H35.3
ICD-10 code description
Degeneration of macula and posterior pole

Primary outcomes

1

Description
Induction time
Timepoint
monthly after initiation of intervention
Method of measurement
Questionnaire

2

Description
number of needed injections to complete Induction phase
Timepoint
monthly after initiation of intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
final Best Corrected Visual Acuity (BCVA)
Timepoint
12 months after initiation of intervention
Method of measurement
Early Treatment Diabetic Retinopathy Study (ETDRS) charts

2

Description
size of neovascularization
Timepoint
12 months after initiation of intervention
Method of measurement
Questionnaire

3

Description
foveal thickness
Timepoint
12 months after initiation of intervention
Method of measurement
Questionnaire, Optical Coherence Tomography (OCT) records

4

Description
Relapse: new onset of Intraretinal fluid, Subretinal fluid, Hemorrhage or decrease of BCVA more than 5 scores)
Timepoint
12 months after initiation of intervention
Method of measurement
Questionnaire: physical examination, OCT scan, ETDRS Charts

Intervention groups

1

Description
Control group: placebo capsules, will be given twice a day for 4 months in addition to standard treatment according to Treat and Extend Regimen. In this regimen, All subjects will receive 1.25 mg intravitreal injections of Bevacizumab administered monthly for 3 treatments. After 3 initial treatments, the interval between treatments will be tailored based on exudative disease activity: eyes will be treated at each visit, no more frequently than every 4 weeks and no less frequently than every 12 weeks. At each visit, patients will be classified as having a dry or wet macula and will be treated monthly until a dry Macula will be achieved (resolution of intraretinal and subretinal fluid on SD OCT and on resolution of subretinal and intraretinal hemorrhage related to exudative AMD). When a dry macula is achieved, the interval between visits will be increased by 2 weeks. If recurrent exudative disease activity will be identified, the interval between visits will be reduced by 2 weeks. These processes will continue until a dry macula will be achieved.
Category
Placebo

2

Description
Intervention group 1: in this group, patients will take Doxycycline, 100 mg cap, twice a day, in addition to standard treatment according to Treat and Extend Regimen for 4 months. All subjects will receive 1.25 mg intravitreal injections of Bevacizumab administered monthly for 3 treatments. After 3 initial treatments, the interval between treatments will be tailored based on exudative disease activity: eyes will be treated at each visit, no more frequently than every 4 weeks and no less frequently than every 12 weeks. At each visit, patients will be classified as having a dry or wet macula and will be treated monthly until a dry Macula will be achieved (resolution of intraretinal and subretinal fluid on SD OCT and on resolution of subretinal and intraretinal hemorrhage related to exudative AMD). When a dry macula is achieved, the interval between visits will be increased by 2 weeks. If recurrent exudative disease activity will be identified, the interval between visits will be reduced by 2 weeks. These processes will continue until a dry macula will be achieved.
Category
Treatment - Drugs

3

Description
Intervention group 2: in this group, patients will take Doxycycline, 100 mg cap, twice a day until the completion of induction phase of Treat and Extend Regimen protocol in addition to standard treatment according to Treat and Extend Regimen. All subjects will receive 1.25 mg intravitreal injections of Bevacizumab administered monthly for 3 treatments. After 3 initial treatments, the interval between treatments will be tailored based on exudative disease activity: eyes will be treated at each visit, no more frequently than every 4 weeks and no less frequently than every 12 weeks. At each visit, patients will be classified as having a dry or wet macula and will be treated monthly until a dry Macula will be achieved (resolution of intraretinal and subretinal fluid on SD OCT and on resolution of subretinal and intraretinal hemorrhage related to exudative AMD). When a dry macula is achieved, the interval between visits will be increased by 2 weeks. If recurrent exudative disease activity will be identified, the interval between visits will be reduced by 2 weeks. These process will continue until a dry macula will be achieved.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Comprehensive Center of Excellence in Ophthalmology
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Tehran

University of Medical Sciences

Full name of responsible person
Masud Yunesian

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Grant name

Grant code / Reference number
95-01-43-31872

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

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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Full name of responsible person
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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