Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Visual acuity and central macular thickness in the hemorrhagic choroid neo-vascularization due to age-related macular degeneration with intravitreal Avastin injection compared with intravitreal injection of tissue plasminogen activator with avastin

Protocol summary

Summary

Our goal is to assess potential effects of improving visual acuity and macular thickness reduction using intravitreal tissue plasminogen activator with intravitreal Avastin compared to intravitreal Avastin in patients with hemorrhagic choroid neo-vascularization. Patients with clinical and laboratory hemorrhagic choroid neovascularization diagnosed due to age-related macular degeneration referring to Nikookari hospital clinics of Tabriz, Iran that require treatment with intravitreal Avastin will be selected. Sample size: 54 eyes of patients by simple single-center randomized method assigned to two groups. Control group are receiving intravitreal Avastin standard treatment and the intervention group receiving intravitreal Avastin in addition to tissue plasminogen activator. Visual acuity by using the Snellen chart and macular thickness by using macular OCT will be checked before treatment, one month and six months after treatment. Inclusion criteria: recent onset of CNV due to AMD within a month. Exclusion criteria: diabetic and inflammatory maculopathy and retinal injury and clearly damage to the optic nerve.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511064166N6**
Registration date: **2016-03-31, 1395/01/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-31, 1395/01/12

Registrant information

Name
Rana Daei Sorkhabi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 41 1655 1332

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rana@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Visual acuity and central macular thickness in the hemorrhagic choroid neo-vascularization due to age-related macular degeneration with intravitreal Avastin injection compared with intravitreal injection of tissue plasminogen activator with avastin

Public title

Effect of intravitral injection of tissue plasminogen activator on visual acuity and retinal macular thickness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hemoragic CNV due to AMD; early onset of symptom in the last month; history of good visual acuity in affected eye Exclusion criteria: history of vitroretinal surgery; uveitis with vitroretinal impairment; corneal disease for example keratoconous, dystrophy and degeneration; any medial hazeness for example vitrous hemorrhage, significant cataract ,...; pathologic myopia; diabetic retinopathy macular edema, retinal detachment, retinal vascular disorder; significant optic nerve injury

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabriz University of Medical Sciences

Street address

Tabriz - azadi avenue - golgasht street - University of Medical Sciences - Central Building No. 2 - Third floor Vice Chancellor for Research and Technology

City

tabriz

Postal code

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

TBZMED.REC.1394.1006

Health conditions studied

1

Description of health condition studied

Age related macular degeneration

ICD-10 code

H35.3

ICD-10 code description

Degeneration of macula and posterior pole

Primary outcomes

1

Description

Visual acuity

Timepoint

Before the intervention, one month and 6 months later

Method of measurement

Snellen chart

2

Description

Macular thickness

Timepoint

Prior to the study, one month and six months later

Method of measurement

Macular OCT

Secondary outcomes

empty

Intervention groups

1

Description

Intravitreal injection of 75 micrograms of tissue plasminogen activator plus 1.25 mg of Avastin in the intervention group

Category

Treatment - Drugs

2

Description

intravitreal injection of 1.25 mg Avastin in the control group (standard treatment)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikokari Eye Hospital in Tabriz

Full name of responsible person

Rahman Beyrami, ophtalmology resident

Street address

Nikokari Eye Hospital, Abbasi St.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences-Vice Chancellor for Research and Technology

Full name of responsible person

Dr. Mohamed Reza Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences-Vice Chancellor for Research and Technology

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

Tabriz University of Medical Sciences

Full name of responsible person

Rahman Beyrami

Position

Ophtalmology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr. Mohamad Hussein Ahoor

Position

Ophtalmologist - vitroretinal Fellowship

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Person responsible for updating data

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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