Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effect of intavitreal injection of erythropoeitin with intravenous erythropoeitin on visual function of patients with non-arteritic anterior ischemic optic neuropathy with control group

Protocol summary

Summary

Objective: to compare effect of intravitreal and intravenous injection of erythropoeitin on visual function of patients with non-arteritic anterior ischemic optic neuropathy with control group Design: randomized, blinded, single center clinical trial Participants : inclusion criteria : patients with non-arteritic anterior ischemic optic neuropathy with decreased vision, optic disc swelling, compatible visual field defects; normal ESR and CRP; lack of signs and sypmtoms suggesting giant cell arteritis(headache, jaw claudication); normal Na, Mg, K, liver function tests, Hgb; refered within 2 weeks after onset of decreased vision. Excluson criteria: high ESR and CRP; signs and sypmtoms suggesting giant cell arteritis; abnormal Na, Mg, K, liver function tests, Hgb; refered after 2 weeks of decreased vision; current smoking habbit Sample size : 150 patients (50 patients for each group) Conduct and interventions : patients will bw asignned randomly to 3 groups : group1 will be observed. Group 2 will have intravitreal injection of erythropoeitin; and group 3 will be undergone intravenous injection of erythropoeitin Main outcome measures : visual acuity; visual field; retinal nerve fiber layer thickness

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102275914N2**
Registration date: **2011-03-05, 1389/12/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-05, 1389/12/14

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Eye research center, Rasoul Akram Hospital, Tehran University of Medical Sciences

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2012-02-29, 1390/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of intavitreal injection of erythropoeitin with intravenous erythropoeitin on visual function of patients with non-arteritic anterior ischemic optic neuropathy with control group

Public title

Effect of erythropoeitin on visual function of patients with non-arteritic anterior ischemic optic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients with non-arteritic anterior ischemic optic neuropathy with decreased vision, optic disc swelling, compatible visual field defects; normal ESR and CRP; lack of signs and sypmtoms suggesting giant cell arteritis(headache, jaw claudication); normal Na, Mg, K, liver function tests, Hgb; refered within 2 weeks after onset of decreased vision. Excluson criteria: high ESR and CRP; signs and sypmtoms suggesting giant cell arteritis; abnormal Na, Mg, K, liver function tests, Hgb; refered after 2 weeks of decreased vision; current smoking habbit

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

8th Floor, Rasoul Akram Hospital, Niayesh St., Sattarkhan Ave.

City

Tehran

Postal code

Approval date

2010-11-22, 1389/09/01

Ethics committee reference number

134

Health conditions studied

1

Description of health condition studied

ischemic optic neuropathy

ICD-10 code

H47.0

ICD-10 code description

Disorders of optic nerve, not elsewhere classified

Primary outcomes

1

Description

Visual acuity

Timepoint

first and 7th day, 1st and 3rd and 6th month

Method of measurement

Ṡellen chart and convertion to logMAR

Secondary outcomes

1

Description

Visual field

Timepoint

1st and 7th day, 1st and 3rd and 6th month

Method of measurement

Humphery perimetry, SITA standard 24-2 strategy

2

Description

Retinal nerve fiber layer thickness

Timepoint

1st day and 1st,3rd,6th ,

Method of measurement

Optical coherence tomogram(OCT)

Intervention groups

1

Description

Group3: Admitting the patient. 1st day : Slow intravenous infusion of 20000 units of erythropoeitin with controlling vital signs every 15minutes during infusion; recording visual acuity 2nd day : as above 3rd day : as above

Category

Treatment - Drugs

2

Description

Group 2 : Intra vitreal injection of 2000 units of erythropoeitin in 0.2cc with 29 gauge needle under sterile condition in operating room, 4 mm from limbus in phakic and 3 mm from limbus in aphakic or pseudophakic patients

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul akram hospital

Full name of responsible person
Dr. Reza Soudi

Street address
8th Floor, Ophthalmology clinics and emergency ward, Rasoul Akram Hospital, Niayesh St., Sattarkhan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran university of medical sciences

Full name of responsible person
Dr. Mehdi Modarreszade

Street address
8th Floor, Rasoul Akram Hospital, Niayesh St., Sattarkhan Ave.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, 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

Contact

Name of organization / entity
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Position
Resident of Ophthalmology

Other areas of specialty/work

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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