

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effects of topical interferon Gamma 1b in the treatment of uveitic cystoid macular edema

Protocol summary

Summary

Our aim, in this study, is to evaluate the effects of interferon Gamma 1b in the treatment of uveitic cystoid macular edema. Some principal inclusion criteria are, to have uveitis at least 3 months before the participation in the study together with macular cystoid edema secondary to uveitis in at least one eye, Some principal exclusion criteria are pregnancy or breast feeding; occurrence of intolerable adverse effects. Due to a restriction in count of eligible patients, 10 subjects (both males and females) aged between 18 to 60 referring to the ophthalmology clinics of Nikukari hospital , Tabriz, Iran, during a 1 year period starting from 2011-03-11, would be included. A basal Optical Coherence Tomography of the macula will be performed for all the individuals before the administration of the drug and then one drop of considered eye drop containing 10 micrograms in 0.05 ml of interferon Gamma 1b solution (equivalent to mentioned drug's vial concentration) would be instilled in involved eye(s) weekly for 3 weeks. Optical coherence tomography (as a primary outcome measure) would be repeated to obtain the central macular thickness one week after instillation of each dose and 3 months after the instillation of the last dose. In each visit measurement of intraocular pressure and intraocular inflammation (as other primary outcome measures) would be checked using tonometer and slit lamp, respectively. Visual acuity (as the secondary outcome measure) will be tested, as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105236568N1**

Registration date: **2011-12-28, 1390/10/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-28, 1390/10/07

Registrant information

Name

Leila Alizadeh ghavidel

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1655 1332

Email address

alizadehl@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-03-11, 1389/12/20

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of topical interferon Gamma 1b in the treatment of uveitic cystoid macular edema

Public title

Interferon Gamma 1b as a treatment for macular edema caused by uveitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (to have medial, posterior or pan-uveitis at least 3 months before the participation in the study together with macular cystoid edema secondary to uveitis in at least one eye; to have visual acuity equal or greater than 20/200; to be 18 to 60 year-old; to have a central macular thickness greater than 250 micrometers)
Exclusion criteria: (pregnancy or breast feeding; occurrence of intolerable adverse effects; to have a history of herpetic keratitis and multiple sclerosis; to have an active infection which needs an urgent treatment; history of chronic or recurrent infections)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Medical University

Street address

Tabriz Medical University, Daneshgah square

City

Tabriz

Postal code

Approval date

2011-03-14, 1389/12/23

Ethics committee reference number

9035

Health conditions studied

1

Description of health condition studied

Uveitic cystoid macular edema

ICD-10 code

H35.8, H20

ICD-10 code description

other specified retinal disorders, uveitis

Primary outcomes

1

Description

Central Macular Thickness

Timepoint

Before the initiation of the intervention, one week after instillation of each dose for 3 weeks, 3 months after the finishing of the study

Method of measurement

Using Optical Coherence Tomography (OCT), micrometer

2

Description

Intraocular pressure

Timepoint

Before the initiation of the intervention, one week after instillation of each dose for 3 weeks, 3 months after the finishing of the study

Method of measurement

Using tonometer, mmHg

3

Description

Intraocular inflammation

Timepoint

Before the initiation of the intervention, one week after instillation of each dose for 3 weeks, 3 months after the finishing of the study

Method of measurement

Using slit lamp, mild or moderate or severe

Secondary outcomes

1

Description

Visual acuity

Timepoint

Before the initiation of the intervention, one week after instillation of each dose for 3 weeks, 3 months after the finishing of the study

Method of measurement

Snellen chart, in a fraction of 200

Intervention groups

1

Description

one drop of considered eye drop containing 10 micrograms in 0.05 ml of interferon Gamma 1b solution, weekly for 3 weeks will be instilled in involved eye(s)

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Nikukari hospital

Full name of responsible person

MohammadReza Eskandari

Street address

Clinics ward, Nikukari hospital, Abbasi street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

AliReza Ostad Rahimi

Street address

Chandler for research, Tabriz Medical University,
Daneshgah square

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

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 Medical University

Full name of responsible person

MohammadReza Eskandari

Position

Ophthalmology resident, student

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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