Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 tumography (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 intraoccular pressure and intraoccular 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
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Iran (Islamic Republic of)
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+98 41 1655 1332
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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 keritiitis 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
Intraoccular 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
Intraoccular 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

Treatment - Drugs

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

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Position
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Fax

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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