Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Study of the Efficacy of Infliximab in comparison with Cyclophosphamide in refractory uveitis in Behcet’s diseases

Protocol summary

Study aim
Comparison of the efficacy of Infliximab with cyclophosphamide on resistant uveitis in Behcet disease

Design
The investigation is designed as a double-blind pilot study on Behcet's patients with resistance to uveitis. Patients are randomly divided into two groups of ten by coin throwing. In one group the effect of cyclophosphamide and in the other group the effect of Infliximab will be evaluated according to the data protocol.

Settings and conduct
This study is done for the first time (in the form of a pilot) as a double blinded interventional study on 20 patients with Behcet's disease with refractory uveitis. The patients are randomly divided into two groups and will be treated. In the first group, treatment with infliximab, prednisolone, azathioprine and methotrexate or cyclosporine will be performed. The second group will be treated with cyclophosphamide, prednisolone, azathioprine and methotrexate or cyclosporine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Behcet's disease Resistance to commonly used uveitis Retinal vesiculitis Exclusion criteria: Patient consent Contraindication for prescribing infliximab or cyclophosphamide No response to medication

Intervention groups
Group 1 includes Behcet patients with refractory uveitis treatment receiving Infliximab Group 2 includes Behcet patients with refractory uveitis treatment receiving Endoxan

Main outcome variables
The total inflammatory activity index calculated based on parameters including the anterior uveitis, posterior uveitis and retinal vasculitis. The inflammatory activity index of the disease is based on the visual acuity that is calculated based on parameters including the anterior uveitis, posterior uveitis and retinal vasculitis and visual acuity.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180110038297N1**
Registration date: **2018-05-02, 1397/02/12**
Registration timing: **retrospective**

Last update: **2018-05-02, 1397/02/12**
Update count: **0**

Registration date
2018-05-02, 1397/02/12

Registrant information

Name
Azadeh Behnam Ghader

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Study of the Efficacy of Infliximab in comparison with Cyclophosphamide in refractory uveitis in Behcet’s diseases

Public title
Efficacy of Infliximab comparing with Cyclophosphamide in refractory uveitis in Behcet’s diseases

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Behcet’s disease Refractory uveitis Retinal vesiculitis

Exclusion criteria:
Patient dissatisfaction Contraindications for administration of Infliximab or cyclophosphamide Non response to medication

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment as coin throw

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study in order to blind the investigator, another person (a nurse) who does not participate in the study, will randomly assign both of Endoxan and Infliximab to each patient. Beyond this, drugs will be the same in color and equally used in serum to blind the patient. Patients’ information together with the type of drugs, will be stored in sealed envelopes and will be kept by the nurse until the end of follow-up and recording of the consequences or any serious complications for the patient.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Zanjan University of Medical Sciences, Jomhouri Eslami Blvd, Azadi Square, Zanjan

City
Zanjan

Province
Zanjan

Postal code
4515777978

Approval date
2017-01-17, 1395/10/28

Ethics committee reference number
ZUMS.REC.1395.233

Health conditions studied

1

Description of health condition studied
Refractory uveitis in patients with Behcet

ICD-10 code
M35.2

ICD-10 code description
Behcet's disease

Primary outcomes

1

Description
Total Inflammatory Activity Index

Timepoint
Measuring the total inflammatory activity index at the beginning of the study (prior to the intervention) and 2, 6 and 8 weeks after starting Infliximab, as well as measuring the index at the beginning of the study (before the intervention) and 1, 2 and 3 months later Start taking Endoxan

Method of measurement
Total inflammatory activity index is defined as right eye ([AU ×1] + [PU ×2] + [RV ×3]) + left eye ([AU ×1]+[PU ×2] + [RV ×3]) in which the PU stands for Posterior Uveitis, AU denotes Anterior Uveitis and RV shows Retinal Vasculitis.

2

Description
Total Adjusted Disease Activity Index

Timepoint
Measuring the total inflammatory activity index at the beginning of the study (prior to the intervention) and 2, 6 and 8 weeks after starting Infliximab, as well as measuring the index at the beginning of the study (before the intervention) and 1, 2 and 3 months later Start taking Endoxan

Method of measurement
Total Adjusted Disease Activity Index is defined as TIAI + right eye ([VA-10] ×2) + left eye ([VA-10] ×2) in which TIAI stands for Total inflammatory activity index and VA is the visual acuity

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The 10-membered group receiving infliximab by intravenous injection at a dose of 3 mg / kg in weeks 0, 2, 6 and then 8 weeks later (a total of four injections) with methotrexate 25 mg weekly (or cyclosporine 5 mg / kg daily), azathioprine is given as mg / kg 3 and daily prednisone 1 mg / kg.
Category
Treatment - Drugs

2

Description
Control group: Control group: The 10-person group received Endoxan with intravenous injection of 1000 mg per month (four consecutive months) with azathioprine (mg / kg 3) daily, methotrexate 25 mg weekly (or cyclosporine 5 mg / kg daily) and Prednisolone 1 mg / kg daily Became
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Rheumatology of Valiasr Hospital in Zanjan
Full name of responsible person
Alireza Sadeghi
Street address
Education and treatment center of Valiasr, Valiasr square, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
علیرضا شغلی
Street address
Zanjan University of Medical Sciences, Azadi Square
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valiasr@zums.ac.ir
Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=9
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Azadeh Behnam Ghader
Position
Internal Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
For patients, visual acuity, anterior uveitis, posterior uveitis and retinal vasculitis are measured before and during treatment, and the results are disseminated.
When the data will become available and for how long
Six months after the publication of the results
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
In order to continue the study or do the same scientific research
From where data/document is obtainable
Azadeh Behnam Ghader
What processes are involved for a request to access data/document
The interested scholar can receive the necessary information by email with the respective responsible person and provide the personal details and field of research after a maximum of one week.
Comments