

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3773 2240

##### Email address

abehnamghader@zums.ac.ir

##### 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, Jomhuri 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

##### City

Zanjan

##### Province

Zanjan

##### Postal code

7797845157

##### Phone

+98 24 3377 0801

##### Fax

+98 24 3377 0757

##### Email

valiasr@zums.ac.ir

##### Web page address

http://zums.ac.ir/index.php?slc\_lang=fa&sid=9

## 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

##### City

Zanjan

##### Province

Zanjan

##### Postal code

7797845157

##### Phone

+98 24 3377 0801

##### Email

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

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

Education and treatment center of Valiasr, Valiasr square, Zanjan

##### City

Zanjan

##### Province

Zanjan

**Postal code**  
7797845157  
**Phone**  
+98 24 3377 0801  
**Email**  
abehnamghader@zums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Azadeh Behnam Ghader  
**Position**  
Internal Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Education and treatment center of Valiasr, Valiasr square, Zanjan  
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**Email**  
abehnamghader@zums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Azadeh Behnam Ghader  
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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