

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### Etanercept Versus Placebo in Ocular Manifestations of Behcet's Disease, a single Blind Controlled trial

#### Protocol summary

##### Summary

The goal of this study is to evaluate the efficacy of Etanercept in Ocular Manifestations of Behcet's Disease. The main Inclusion Criteria is Behcet's Disease with Active posterior uveitis and/or retinal vasculitis. The main Exclusion Criteria is Being under cytotoxic drugs or having received them during the past 2 months. The study population is Behcet's patients whose disease was diagnosed according to the International Criteria for Behcet's disease (ICBD). To achieve the goal of the study, drug efficacy will be compared between 40 patients in each intervention and control arms. Patients will be randomly assigned to Etanercept or control group. Patients in the intervention group will receive Etanercept as 50 mg weekly IM injection for one year. All patients will receive Methotrexate as 15 mg weekly during the one year period of the trial and prednisolone as 30 mg daily, at the entry to the study. The dose of prednisolone will be adjusted and tapered if frank improvement or remission occurs. The duration of the study will be one year and visual acuity, disease activity index for anterior uveitis, posterior uveitis, retinal vasculitis, Total Inflammatory Activity Index (TIAI), and Total Adjusted Disease Activity Index (TADAI) will be measured for each eye and each patient every 2 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138901292641N2**  
Registration date: **2010-04-18, 1389/01/29**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-04-18, 1389/01/29

#### Registrant information

##### Name

Fereydoun Davatchi

##### Name of organization / entity

Rheumatology Research Center, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8802 6956

##### Email address

davachif@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2010-06-22, 1389/04/01

#### Expected recruitment end date

2011-06-22, 1390/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Etanercept Versus Placebo in Ocular Manifestations of Behcet's Disease, a single Blind Controlled trial

#### Public title

Etanercept Versus Placebo in Ocular Manifestations of Behcet's Disease, a single Blind Controlled trial

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: Behcet's Disease according to the International Criteria for Behcet's disease (ICBD), Active posterior uveitis and/or retinal vasculitis  
Exclusion

Criteria: Visual acuity inferior to 1/10 on Snellen chart,  
Being under cytotoxic drugs or having received them in  
the past 2 months, Not being able to follow the one year  
treatment and the regular follow ups

## Age

From **16 years** old to **70 years** old

## Gender

Both

## Phase

4

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## 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

### 1

#### Registry name

clinicaltrials.gov

#### Secondary trial Id

NCT00931957

#### Registration date

2010-01-26, 1388/11/06

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

6th floor-central university department-Ghods street-  
Keshavarz Avenue

##### City

Tehran

##### Postal code

#### Approval date

2008-02-16, 1386/11/27

#### Ethics committee reference number

5807

## Health conditions studied

### 1

#### Description of health condition studied

Ocular involvement in Behcet's disease

## ICD-10 code

M35.2

## ICD-10 code description

behcet's disease

## Primary outcomes

### 1

#### Description

Inflammatory Activity Index

#### Timepoint

2 months

#### Method of measurement

Total Inflammatory Activity Index

### 2

#### Description

Visual acuity

#### Timepoint

2 months

#### Method of measurement

Total Inflammatory Activity Index

## Secondary outcomes

### 1

#### Description

Total Inflammatory Activity Index (TIAI)

#### Timepoint

2 months

#### Method of measurement

ophthalmologist's record

### 2

#### Description

Visual acuity

#### Timepoint

2 months

#### Method of measurement

ophthalmologist's record

### 3

#### Description

disease activity index for anterior uveitis

#### Timepoint

2 months

#### Method of measurement

ophthalmologist's record

### 4

#### Description

retinal vasculitis

#### Timepoint

2 months

#### Method of measurement

ophthalmologist's record,Top con TR angiography 50S,

skiascopy,ocular coherenttomography

## 5

### Description

Total Adjusted Disease Activity Index (TADAI)

### Timepoint

2 months

### Method of measurement

ophthalmologist's record

## 6

### Description

disease activity index for posterior uveitis

### Timepoint

2 months

### Method of measurement

ophthalmologist's record

## Intervention groups

## 1

### Description

Etanercept 50 mg weekly for one year as well as Methotrexate as 15 mg weekly during the one year plus prednisolone as 30 mg daily, at the entry to the study. The dose will be adjusted and tapered if frank improvement or remission occurs

### Category

Treatment - Drugs

## 2

### Description

Methotrexate as 15 mg weekly during the one year plus prednisolone as 30 mg daily, at the entry to the study. The dose will be adjusted and tapered if frank improvement or remission occurs

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Behcet's Clinic-Rheumatology Research Center

#### Full name of responsible person

Bahar Sadeghi, MD

#### Street address

Shariati hospital

#### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

### Name of organization / entity

Tehran University Of Medical Sciences

### Full name of responsible person

Haniyeh Rostamabadian

### Street address

Tehran University Of Medical Sciences

### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

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

Researcher-General Physician

#### Full name of responsible person

Bahar Sadeghi MD

#### Position

Rheumatology Research Center

#### Other areas of specialty/work

#### Street address

Shariati Hospital

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+98 21 8802 6956

#### Fax

#### Email

bahar@bahars.net

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Rheumatology Research Center

#### Full name of responsible person

Prof. Fereydoun Davatchi

#### Position

Doctorate degree, Rheumatology subspeciality

#### Other areas of specialty/work

#### Street address

Shariati Hospital

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info@rrciran.org  
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## Sharing plan

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rheumatology Research Center  
**Full name of responsible person**  
Shima RoknSharifi MD.  
**Position**  
General Physician-Research Assistant  
**Other areas of specialty/work**  
**Street address**  
Shariati Hospital  
**City**  
Tehran

**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*