

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

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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

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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.
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General Physician-Research Assistant
Other areas of specialty/work
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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