

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effectiveness of 1 mg/day Colchicine in the treatment of patients with ocular involvement in Behcet's Disease

Protocol summary

Summary

Colchicine is one of the common drugs in treating patients with Behcet's disease. This project is conducted with the goal of examining the hypothesis of "effectiveness of adding 1mg Colchicine in Behcet's disease patients with visual involvement was accomplished ". 80 Behcet's patients with active visual involvement (in the form of posterior uveities or retinitis) referring to Behcet's clinic in Shariati hospital whose problem was confirmed with new international criteria, if they had inclusion criteria of the study as well, after signing the consent will be assigned in 2 groups of intervention or control through a balanced block randomization. Participants of 2 groups are Behcet's patients treating with appropriate dose of Prednisolone plus Methotrioxide+Azathioperin+pulse of Ciclophosphamide or combination of them. 1mg daily Colchicine will be added to the treating regimen. The patients will be visited every 3months by an ophthalmologist who is unaware of the group of patient. Total following time is 12 months in 5 visits. Visual acuity and retinal and posterior chamber inflammation index will be recorded and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808062641N1**

Registration date: **2010-01-21, 1388/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-01-21, 1388/11/01

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-01-21, 1388/11/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of 1 mg/day Colchicine in the treatment of patients with ocular involvement in Behcet's Disease

Public title

The effectiveness of 1 mg/day Colchicine in the treatment of patients with ocular involvement in Behcet's Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosed Behcet's disease according to Iran's diagnostic tree criteria, signing the informed

consent, not being pregnant or breast feeding, no history of malignancy, age more than 16, posterior uveitis or retinitis in latest ophthalmological visit
Exclusion criteria: blood dyscrasia, pregnancy, low compliance

Age

From **17 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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

EDRC's Committee of Medical Ethics

Street address

Shariati hospital, Kargar Ave.

City

Tehran

Postal code

14117

Approval date

2009-10-26, 1388/08/04

Ethics committee reference number

FWA00001331

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

decrease/or not relapsing of ocular inflammatory index

Timepoint

3 months

Method of measurement

ophthalmologist's record

Secondary outcomes

1

Description

decrease/or not relapsing ocular IBDDAM

Timepoint

3 months

Method of measurement

Ophthalmologist's record

2

Description

retinal inflammatory index

Timepoint

3 months

Method of measurement

Ophthalmologist's record

3

Description

posterior chamber inflammatory index

Timepoint

3 months

Method of measurement

Ophthalmologist's record

Intervention groups

1

Description

Colchicine 1mg/day during one year PO

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

Asadollah Madadi

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

Rheumatology Research Center

Full name of responsible person

Bahar Sadeghi

Position

General physician-Research assistant- Researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

Rheumatology Research Center

Full name of responsible person

Shima Rokn Sharifi, MD.

Position

General physician-Research assistant

Other areas of specialty/work

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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