Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Prednizolone plus Methotrioxide+Azatioperin+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)

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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 than16, posterior uveitis or retinitis in latest ophtalmological 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 Commettee 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
ophtalmologist's record

Secondary outcomes

1

Description
decrease/or not relapsing ocular IBDDAM

Timepoint
3 months

Method of measurement
Ophtalmologist's record

2

Description
retinal inflammatory index

Timepoint
3 months

Method of measurement
Ophtalmologist's record

3

Description
posterior chamber inflammatory index

Timepoint
3 months

Method of measurement
Ophtalmologist'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
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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