Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Efficacy of pulse methylprednisolon in improvement of posterior segment involvement in Behcet's ocular lesions: a double blind pilot study

Protocol summary

Summary

The goal of this study is to examine the efficacy of 1gram/month pulse methylprednisolone in Behcet's patients with ocular involvement. A total of 34 Behcet's patients referring to Behcet's clinic in shariati hospital whose problem was confirmed with new international criteria of Behcet's disease (ICBD) will be randomly assigned into one of the two equal groups of intervention or control. Behcet's patients are those with ocular involvement who were under the same cytotoxic treatment with cyclophosphamide and azathioprine. For the patients in the intervention group, intravenous infusion of 1000 mg methylprednisolone in 100cc D/w 5% or 100cc D/w5% on 3 consecutive days will be added to treatment diet. Then treatment will begin with ora l prednisolone, 0.5 mg/kg. After that, all the patients were followed up with no other therapeutic intervention. The patients will be visited every 2 months by an ophthalmologist for 6 months in 3 settings. To estimate the ocular inflammation of patients, we use visual acuity, retinal and posterior chamber inflammation index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011235235N1**
Registration date: **2011-01-28, 1389/11/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-01-28, 1389/11/08

Registrant information

Name

Farhad Shahram

Name of organization / entity

Rheumatology Research Center

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Recruitment status

Recruitment complete

Funding source

Rheumatology Research Center, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of pulse methylprednisolon in improvement of posterior segment involvement in Behcet's ocular lesions: a double blind pilot study

Public title

The efficacy of puls methylprednisolone 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 international criteria, New or relapse of retinal vasculitis who received any cytotoxic or glucocorticoid since 2 months ago, or new or relapse of severe posterior uveitis who are candidate for

cyclophosphamide and azathioprine according to their physician Exclusion criteria: not Signing the informed consent, Visual acuity lower than 1/10 by Snellen chart, presence of infectious diseases such as TB, presence of diabetes mellitus, hypertension, heart disease, liver disease, renal disease, or edema, presence of other glucocorticoid consumption contraindications

Age
From **10 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **34**

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
Tehran University of Medical Sciences and Health Services

Street address
Tehran University of Medical Science and Health Services, Enghelab Ave., Tehran

City
Tehran

Postal code

Approval date
2010-11-09, 1389/08/18

Ethics committee reference number
11192

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
Ocular IBDDAM INDEX

Timepoint
Before and 2 months after treatment

Method of measurement
ophthalmologist record

2

Description
Visual acuity

Timepoint
Before intervention and then every 2 months for 6 months

Method of measurement
ophthalmologist record

Secondary outcomes

1

Description
Inflammation in retina

Timepoint
Before and two months after intervention

Method of measurement
ophthalmologist record

Intervention groups

1

Description
Intervention group: Intravenous infusion of 1000 mg methylprednisolone in 100cc D/w 5% on 3 consecutive days at the beginning of treatment

Category
Treatment - Drugs

2

Description
Control group: 100cc D/w5% on 3 consecutive days at the beginning of treatment

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Behcet′s Clinic, Rheumatology Research Center

Full name of responsible person

Dr. Mastaneh Mohammadi

Street address

Shariati Hospital, Kargar Ave., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rheumatology Research Center

Full name of responsible person

Dr. Farhad Shahram

Street address

Rheumatology Research Center, Shariati Hospital, Karg ar Avenue, Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rheumatology Research Center

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

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Mastaneh Mohammadi

Position

Fellowship of Rheumatology

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