

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparing the efficacy of IV methyprednisolone plus oral prednisolone therapy with IV methyprednisolone therapy alone in the treatment of acute demyelinating optic neuritis

Protocol summary

Summary

study purpose:comparing the efficacy of IV methyprednisolone plus oral prednisolone therapy with IV methyprednisolone therapy alone in the treatment of acute demyelinating optic neuritis study design:randomized,double blind,control with placebo,single central,stage 2 of trial, inclusion criteria:patient 15 to 50 years old referred with opti neuritis" that their visual acuity decreased above 50%. exclusion criteria:side effect such as gastrointestinal bleeding...during usage of methyprednisolone puls and oral prednisolone" patients with diabets sample number:60 intervention: oral prednisolone usage inintervention group and placobo in control group. intervention time:10 days. study effect:recovery of visual acuity and color vision

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102724734N1**
Registration date: **2016-04-18, 1395/01/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-18, 1395/01/30

Registrant information

Name

Adel Nejati khoshkbejari

Name of organization / entity

Ahvaz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3375 4564

Email address

nejati.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2015-11-20, 1394/08/29

Expected recruitment end date

2016-02-17, 1394/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the efficacy of IV methyprednisolone plus oral prednisolone therapy with IV methyprednisolone therapy alone in the treatment of acute demyelinating optic neuritis

Public title

prednisolone effect in optic neutitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:patient 15 to 50 years old referred with optic neuritis" that their visual acuity decreased above 50% Exclusion criteria:side effect such as gastrointestinal bleeding ,...during usage of methyprednisolone puls and oral prednisolone" patients with diabet

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomized design: blocking

Secondary Ids

1

Registry name

no registry anywhere

Secondary trial Id

-

Registration date

empty

2

Registry name

در جایی ثبت نشده است

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur university of Medical Sciences

Street address

Central organization, Ahvaz Jundishapur university of Medical Sciences, golestan bolvar, Ahvaz, khoozestan

City

ahvaz

Postal code

Approval date

2015-05-30, 1394/03/09

Ethics committee reference number

ir.ajums.rec.1394.179

Health conditions studied

1

Description of health condition studied

optic neuritis

ICD-10 code

g35-g37

ICD-10 code description

demyelinating diseases of the central nervous system

Primary outcomes

1

Description

visual acuity

Timepoint

before, first day after end of intervention, 1 month, 3 months after intervention

Method of measurement

snellen chart

Secondary outcomes

1

Description

color vision

Timepoint

before, first day after end of intervention, 1 month, 3 months after intervention

Method of measurement

farnsworth d15

Intervention groups

1

Description

intervention group: Tab prednisolone 50 mg po for 10 days, Made by: Abureihan pharmacy

Category

Treatment - Drugs

2

Description

control group: Tab placebo po daily for 10 days, Made by: Jondishapur Ahvaz University of Pharmacy Sciences

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Seyed Ehsan Mohammadyani nejad-assistant
professor of neurology

Street address

Khoozestan-Ahvaz-Golestan-Golestan hospital-
Neurology ward

City

ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research,Ahvaz jundishapur
University of Medical Sciences

Full name of responsible person

nader saki

Street address

Ahvaz jundishapur University of Medical Sciences,
central organization,Golestan bolvar, Ahvaz,
khoozestan

City

ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research,Ahvaz jundishapur 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

Ahvaz University Of Medical Sciences

Full name of responsible person

Seyed Ehsan Mohammad Yani Nejad

Position

Assistant Professor of Neurology

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