

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Survey of therapeutic effect of oral prednisolone in compression of placebo in cervical radiculopathy treatment

Protocol summary

Summary

We want to evaluate the therapeutic effect of oral prednisolone in treatment of cervical radiculopathy in a double blind, randomized, placebo controlled trial. We will choose our target sample from those who suffered from cervical radiculopathy. Inclusion criteria are: 1-age 18-60 years. 2- Neck and arm pain for 2 weeks till 1 month. 3- Neck disability index (NDI) at least 15. 4- No chronic use of corticosteroid in past. Exclusion criteria will be: 1- normal EMG after 1 month. 2- happening any adverse effect of corticosteroid or any condition that cause contraindication to use corticosteroid such as pregnancy or hepatic failure. We will choose 2 groups of 30 patients relevant to cervical radiculopathy clinical findings and then we will give them acetaminophen 325 milligram in divided dose to both groups. Tablet of prednisolone 50 milligram for 5 days will be given to one group and then will be tapered. NDI and VRS (visual rating scale) will be calculated before and one week after intervention. We proposed cervical pain as primary subsequent and corticosteroid side effects as secondary one.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801211804N1**

Registration date: **2010-10-23, 1389/08/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-23, 1389/08/01

Registrant information

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Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2009-12-22, 1388/10/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of therapeutic effect of oral prednisolone in compression of placebo in cervical radiculopathy treatment

Public title

Evaluation of prednisolone efficacy in the treatment of cervical radiculopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Age 60-18 years. 2- Arm and neck pain consistent with cervical radiculopathy. 3- Neck disability scale (NDI) at least 15 (moderate disability). 4- The onset of symptoms between 2 weeks to 1 month. 5- No chronic use of corticosteroid. 6- No a history of

previous surgery of cervical spine. Exclusion criteria: 1- Patients with immunosuppression. 2- Red flag of tumor and clinical infection. 3- Symptoms of myelopathy. 4- Liver failure. 5- Schizophrenia. 6- Pregnancy and lactation. 7- Diabetes. 8- Osteoporosis. 9- Glaucoma. 10- Peptic ulcer. 11- Normal EMG after one month.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Isfahan university of medical sciences

Street address

Hezar jarib St.

City

Isfahan

Postal code

Approval date

2010-05-15, 1389/02/25

Ethics committee reference number

289006

Health conditions studied

1

Description of health condition studied

cervical radiculopathy

ICD-10 code

G55.2

ICD-10 code description

Nerve root and plexus compressions in spondylosis

Primary outcomes

1

Description

pain

Timepoint

week

Method of measurement

NDI (neck disability index) and VRS (visual rating scale)

Secondary outcomes

1

Description

drug side effect

Timepoint

week

Method of measurement

patient report

Intervention groups

1

Description

First group: Acetaminophen 325 milligram in 3 doses daily and Prednisolone 50 milligram oral, daily for 5 days and then will be tapered in 5 days

Category

Treatment - Drugs

2

Description

Second group: Acetaminophen 325 milligram in 3 doses daily and placebo for 5 days and then will be tapered in 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

neurology clinic of Kashani hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

Majid Ghasemi

Street address

Kashani hospital

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Private

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**

Isfahan university of medical sciences

Full name of responsible person

Majid Ghasemi

Position

faculty member

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Majid Ghasemi

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address****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*