Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

Name

Majid Ghasemi

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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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 immunosupression. 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
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Person responsible for updating data

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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