

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Investigating The Effects of Short Term Oral Corticosteroid Treatment in Patients with Acquired Lumbar Canal Stenosis.

Protocol summary

Study aim

The Therapeutic Effect of Short Term Oral Corticosteroid Treatment in Patients with Acquired Lumbar Canal Stenosis.

Design

Double-blinded Randomized Placebo-Controlled Clinical Trial

Settings and conduct

Patients with clinical sign and symptoms of acquired lumbar spinal stenosis referred to the Orthopedic Clinic of Isfahan University of Medical Sciences are divided into two Groups. Group 1 received prednisolone tablets (10 mg per day) for one week and treated with Meloxicam, Pantoprazole, Vitamin E for 20 Days. The Group 2 was treated with Placebo, Meloxicam, Pantoprazole, Vitamin E for 20 days, and the clinical symptoms of the patient were compared before intervention and 2 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: written informed consent forms, age>18 years, ALSS, and no history of corticosteroid susceptibility. Exclusion criteria: dissatisfaction of the patients to continue the project, severe allergic reaction to oral corticosteroid, have comorbidities (e.g. gastroesophageal reflux disease, dyspepsia, hypertension, renal failure, diabetes mellitus, BMI>30 kilograms per square meter), recent infection within 3 months ago or hospital admission for the same reasons, neuromuscular disease, history of consuming any corticosteroid in the last three months for any kind of disease, history of any surgery on the spine, history of gastrointestinal bleeding, and the need for spinal surgery or additional medications during the study.

Intervention groups

The intervention group received an additional oral prednisolone 10 mg each day for one week. The control group received a placebo just like the real prednisolone.

Main outcome variables

Ability to Walk painlessly Oswestry Disability Index
Severity of pain

General information

Reason for update

Revising the RCT protocol for elucidating the process of the study and adding important information and declaring the end of the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20180729040636N1**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **prospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **1**

Registration date

2019-01-14, 1397/10/24

Registrant information

Name

Hossein Akbari aghdam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2085

Email address

akbariaghdam@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-18, 1397/10/28

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2019-04-09, 1398/01/20

Trial completion date

2019-06-20, 1398/03/30

Scientific title

Investigating The Effects of Short Term Oral Corticosteroid Treatment in Patients with Acquired Lumbar Canal Stenosis.

Public title

Effect of Corticosteroid in Lumbar Spinal Canal Stenosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written Consent to Enter Study Age Over 18 Years Acquired Lumbar Spinal Canal Stenosis No History of Corticosteroid Susceptibility

Exclusion criteria:

Concomitant With Other Systemic Diseases, Such as Blood pressure, Diabetes, BMI>30 kg/m2, Gastroesophageal reflux disease, dyspepsia, renal failure, neuromuscular disorders History of Corticosteroid Use in The Last Three Months. Needing spinal surgery for Acquired Spinal Canal Stenosis Recent infection within 3 months ago or hospital admission for the same reasons Incidence of drug complications/severe allergic reaction to oral corticosteroid history of any surgery on the spine history of gastrointestinal bleeding

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Actual sample size reached: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were allocated into intervention or control group using block randomization method to keep an even randomization ratio of (1:1). If the patient had inclusion criteria and did not excluded from the study according to above mentioned protocol, the random number generating software was used to determine their designated group. Numbers were between 0-9. If the number was even, the letter "A" was wrote at the top of their checklist by the examining physician, and if the number was odd, the letter "B" was used. Then, the next patient had to be assigned to the opposite group. This process repeated for the upcoming patients and continued until we reached our estimated sample size. After completing the study and before starting the data analysis process, the encrypted letters were revealed by the pharmaceutical company. The letter "A" was assigned to the intervention group and the letter "B" was

assigned to the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was conducted with double-blinded method. Neither the patients who were included in this study nor the researchers knew about the assignments of groups to either intervention or control. After determining the designated letter, the patients were visited by another researcher who gave the drugs to the patients. A blinded pharmacist who worked in our university hospital pharmacy bought the drugs from the pharmaceutical companies, put them in the designated group ("A" (intervention) or "B" (control) according to the pharmaceutical company policies), and gave the specific package of drugs to the patients (both of them had three active drugs, prednisolone or placebo were different between those bags) with full information of how to use them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences & Health Services, Building No. 4, Hazar Jarib Street

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶-۷۳۴۶۱

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.149

Health conditions studied

1

Description of health condition studied

Acquired Lumbar Spinal Canal stenosis

ICD-10 code

M48.06

ICD-10 code description

Spinal stenosis, lumbar region

Primary outcomes

1

Description

Walking Distance

Timepoint

Before the Intervention and 2 Months Later.

Method of measurement

Metre

2

Description

Oswestry Disability Index from Oswestry Low Back Pain questionnaire

Timepoint

Before the Intervention and 2 Months Later.

Method of measurement

OSWESTRY LOW BACK PAIN SCORE QUESTIONNAIRE

Secondary outcomes

1

Description

Severity of pain

Timepoint

Before the Intervention and 2 Months Later

Method of measurement

PAIN Numerical Rating Scale

2

Description

Low Back Pain

Timepoint

Before the Intervention and 2 Months Later

Method of measurement

Check List

Intervention groups

1

Description

Intervention Group: Prednisolone 10 mg per day for one week, Meloxicam 7.5 mg per day, Vitamin E 400 IU and Pantoprazole 20 mg for 20 days

Category

Treatment - Drugs

2

Description

Control Group: Meloxicam 7.5 mg per day, Vitamin E 400 IU and Pantoprazole 20 mg for 20 days, and placebo for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of Alzahra Hospital

Full name of responsible person

Hossein Akbariaghdam

Street address

Alzahra Hospital, Soffeh Street, Isfahan

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5149

Email

Akbariaghdam@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Orthopedic Clinic of Kashani Hospital

Full name of responsible person

Hossein Akbariaghdam

Street address

Kashani Hospital., kashani Street, Isfahan

City

Esfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

Akbariaghdam@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Akbariaghdam

Street address

Isfahan University of Medical Science, Hezar Jereb Street, Isfahan

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Akbariaghdam@med.mui.ac.ir

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Akbaryaghdam

Position

Assistant Professor of Orthopedics

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Kashani Hospital

City

Esfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3620 2085

Email

Akbaryaghdam@med.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Akbaryaghdam

Position

Assistant Professor of Orthopedics

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Kashani Hospital, Kashani Street, Isfahan

City

Esfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3620 2085

Email

Akbaryaghdam@med.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Akbaryaghdam

Position

Assistant Professor of Orthopedics

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Kashani Hospital, Kashani Street

City

Esfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3620 2085

Email

Akbaryaghdam@med.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available