

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of clinical and radiological results in patients with osteodiscosis with spinal instability operated by posterior aperture without cage

Protocol summary

Study aim

Clinical findings of patients with osteodiscitis with spinal instability without cage

Design

This open label clinical trial study is a prospective group that will be conducted in one year in Al-Zahra Medical Center under the auspices of Isfahan University of Medical Sciences. 34 people will enter the study

Settings and conduct

Our study will be performed in patients with spinal instability due to osteodiscitis in Al-zahra Medical Center. The procedure will be done in posterior approach in the involved column and two upper and lower level. 34 patients will be included and will be followed during 1 year base in VAS pain score. In this study, blindness was not performed and the treatment results in the intervention group will be compared before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient, according to the specialist, is equal to the imaging findings with osteodiscitis with spinal instability. The patient underwent vertebral fusion surgery and anterior vertebral reconstruction without cage. Age range is 45 to 80 years. Patients with involvement of the thoracic, lumbar, and lumbosacral regions will be included in the study. The patient has the consent to participate in the study. Patients who fully participate in one-year follow-up. Exclusion criteria: The patient not recourse for Follow up Patients with unstable systemic conditions Complete destruction of the vertebral body occurs in the upper or lower level of the disc.

Intervention groups

In the intervention group, the surgical technique is performed as a posterior aperture in the involved lobe, and the upper two level and the lower two lobe are involved in the involvement of the damaged disc and

vertebra.

Main outcome variables

Pain, neurological deficit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211012052738N1**

Registration date: **2021-11-13, 1400/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

Registration date

2021-11-13, 1400/08/22

Registrant information

Name

Amirhosein Zohrehvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 9245 7485

Email address

ahz59dr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical and radiological results in patients with osteodiscosis with spinal instability operated by posterior aperture without cage

Public title

clinical and radiological results in patients with osteodiscosis with spinal instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient, according to the specialist, is equal to the imaging findings with osteodiscitis with spinal instability. The patient underwent vertebral fusion surgery and anterior vertebral reconstruction without cage. Age range is 45-80 years. Patients with involvement of the thoracic, lumbar, and lumbosacral regions will be included in the study. The patient has the consent to participate in the study. Patients who fully participate in one-year follow-up.

Exclusion criteria:

The patient not recourse for Follow up Patients with unstable systemic conditions Complete destruction of the vertebral body occurs in the upper or lower level of the disc.

Age

From **45 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

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, Hezar Jerib St., Shiraz Gate

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-10-10, 1400/07/18

Ethics committee reference number

IR.MUI.MED.REC.1400.567

Health conditions studied**1****Description of health condition studied**

Osteodiscits with spinal instability

ICD-10 code

M46.49

ICD-10 code description

Discitis, unspecified, multiple sites in spine

Primary outcomes**1****Description**

Visual analogue scale pain score

Timepoint

Two weeks and one year after surgery

Method of measurement

Using a VAS (visual pain assessment questionnaire)

2**Description**

neurological deficit

Timepoint

Two weeks and one year after surgery

Method of measurement

Clinical examination of the patient by a surgeon

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For this group, the surgical technique is performed as a posterior aperture in the involved lobe and the upper two lobe and the lower two lobe of the involved disc and vertebra.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Majid Rezvani

Street address

Al-Zahra hospital, Sofeh St.,Isfahan,Iran

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Province

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8174675731

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m_rezvani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, hezar jarib S.T

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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

Esfahan University of Medical Sciences

Proportion provided by this source

1

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

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Majid Rezvani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Majid Rezvani

Position

Isfahan

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amirhosein Zohrehvand

Position

fellowship

Latest degree

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable