

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of long-term consequences of the disease in patients with osteodyscitis without correction

Protocol summary

Study aim

Determining the long-term outcomes of the disease in patients with osteodyscitis without cage

Design

This study will be conducted without blinding and on 60 patients. in such a way that the patients will be randomly divided into two groups based on the indication of surgery and based on the randomization part of Excel. In this way, all the names are entered into Excel and we will create a random number in Excel using the Random Number Generation option in the toolback analysis section.

Settings and conduct

This study will be conducted without blinding and on 60 patients. This study will be performed in Al-Zahra Educational and Medical Center in 1401.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient should have osteodyscitis according to the imaging findings. The patient is satisfied to participate in the study. Not addicted to drugs. Do not have autoimmune diseases and other diseases of the spinal cord and spine. Has not taken corticosteroids before or during treatment. Exclusion criteria: lack of consent of the patient to participate in the study

Intervention groups

Cage placement is not performed in the intervention group. In the control group, Cage placement is used like the routine method.

Main outcome variables

Ability to walk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220206053948N1**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **retrospective**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Kiarash Farrahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0551 4677

Email address

k.fishi1991@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of long-term consequences of the disease in patients with osteodyscitis without correction

Public title

consequences of the disease in patients with osteodyscitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should have osteodyscitis according to the expert's imaging findings. The patient has the consent to participate in the study. Do not have drug addiction. Do not have autoimmune diseases and other diseases of the spinal cord and spine Has not taken corticosteroids before or during treatment.

Exclusion criteria:

Lack of patient consent to enter the study

Age

From **15 years** old to **64 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

the patients will be divided into two groups, case and control, based on the indication of surgery completely randomly and based on the randomization part of Excel. In this way, all the names are entered into Excel and we will create a random number in Excel using the Random Number Generation option in the Analysis ToolPak section.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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, Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-12-25, 1400/10/04

Ethics committee reference number

IR.MUI.MED.REC.1400.711

Health conditions studied

1

Description of health condition studied

osteodyscitis

ICD-10 code

M46.2

ICD-10 code description

Osteomyelitis of vertebra

Primary outcomes

1

Description

Ability to walk

Timepoint

Before surgery and 1, 3, 6 and 12 months after surgery

Method of measurement

checklist and Standard questionnaire Japanese Orthopaedic Association on Low Back Pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cage Insertion is not performed. The patient is placed in the prone position and the vertebrae that have already been detected in the MRI are identified and photographed using the c_arm device. The desired place is cut or so-called stripped until the fast is released. After that, the lamina and spinous process of the inflamed vertebrae are removed. Then a path is found to access the disc between the infected vertebrae, the disc is removed and the inflamed parts are also removed (it has started to eat the body of the vertebra, which is called a corpectomy) and it is continued until the edge It starts to bleed and when it reaches this stage, Ben Chips (dead bone) is used and it is poured into the crushed space (between two vertebrae). After that, for the screws that we put, the appropriate part in terms of size and curvature is placed and fixed, and in order for the fusion (connection) to happen outside, Ben Chips is used again. Ben Chips is used in two parts, one for the fusion of broken air and one for the fusion of pedicles and screws at the end. Finally, a drain is used to remove secretions after the operation, and cage placement is not used in this method.

Category

Treatment - Devices

2

Description

Control group: Cage Insertion

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra Hospital

Full name of responsible person

Majid Rezvani

Street address

Al-Zahra Educational and Medical Center, Safa Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavoosh

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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

10

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

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

Contact

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Full name of responsible person

Kiarash Farrahi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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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

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