

# 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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3668 5555

**Email**

alzahra.h@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mansour Siavoosh

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St.

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isfahanuni@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**

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**

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**Position**

Associate Professor

**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**

Kiarash Farrahi

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Al-Zahra Educational and Medical Center, Sofe Street

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**Email**

K.fishi1991@gmail.com

**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