

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

A comparative study of lumbar spine stabilization with 2-stage surgery and cement augmentation in osteoporosis patients: a randomized clinical trial

Protocol summary

Study aim

Comparative study of lumbar spine stabilization with 2-stage surgery and cement reinforcement in osteoporotic patients

Design

The clinical trial has 2 intervention groups with parallel groups. Randomized and without blinding, randomization was done with permutation block design

Settings and conduct

Valiasr Hospital, Qom - patients were operated with 2-stage surgery and cement reinforcement and were evaluated for 12 months.

Participants/Inclusion and exclusion criteria

Patients with osteoporosis, age over 50 years, BMI between 20-30, with degenerative lumbar spine at the level of L1-S1 vertebrae.

Intervention groups

Group A: There are patients who will use bone cement as part of their treatment protocol to strengthen the pedicle screw. Group B: There are patients whose treatment protocol is 2-stage surgery

Main outcome variables

Pain, functional disability, quality of life, disc recurrence, adjacent segment disease, screw loosening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057496N3**

Registration date: **2024-02-26, 1402/12/07**

Registration timing: **retrospective**

Last update: **2024-02-26, 1402/12/07**

Update count: **0**

Registration date

2024-02-26, 1402/12/07

Registrant information

Name

Parisa hajilo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3861 9252

Email address

parisahajilo73@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of lumbar spine stabilization with 2-stage surgery and cement augmentation in osteoporosis patients: a randomized clinical trial

Public title

Comparative study of lumbar spine stabilization with 2-stage surgery and cement augmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Osteoporosis patients with pre-surgery bone density in the range (T-Score->2.5) age range over 50 years body mass index between 20-30 with degenerative lumbar spine complications at L1-S1 level is Exclusion criteria: Patients who could not be reached or lived outside the province patients did not want to enter the study The presence of other pathological factors (cysts or tumors) discopathy in other vertebrae performing any re-surgery during the past year using narcotics or narcotic drugs and smoking suffering from underlying diseases affecting Osteoporosis (rheumatoid arthritis, thyroid disorders...) Age From 50 years old Gender Both Phase N/A Groups that have been masked No information Sample size Target sample size: 66 Randomization (investigator's opinion) Randomized Randomization description The patients will be randomly entered into the study and will be divided into 2 groups A and B based on permutation block design with rows of 4. Group A are patients in whom bone cement will be used as part of their treatment protocol to reinforce the pedicle screw. Group B are patients whose treatment protocol is 2-stage surgery 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 Hamadan University of Medical Sciences Street address 5th floor, Shahid Fahmideh Blvd., University of Medical Sciences, Central Headquarters, Research Square City Hamadan Province Hamadan Postal code	
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۶۵۱۷۸۳۸۷۳۶ Approval date 2024-01-27, 1402/11/07 Ethics committee reference number IR.UMSHA.REC.1402.667 Health conditions studied 1 Description of health condition studied Lumbar spine degeneration ICD-10 code G30-G32 ICD-10 code description Other degenerative diseases of the nervous system Primary outcomes 1 Description Pain Timepoint Before surgery - one month after surgery Method of measurement VAS visual analog scale 2 Description Disability of patients Timepoint Before surgery - one month after surgery Method of measurement Oswestry Disability Index (ODI) Secondary outcomes 1 Description Fution Timepoint 12 months after surgery Method of measurement BSF classification scale 2 Description Pedicle Screw loosing Timepoint 12 months after surgery Method of measurement Dynamic radiography and CT scan images Intervention groups	
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Description

Intervention group first; First intervention group: Lumbar spine stabilization surgery in one step along with pedicle screw reinforcement with bone cement

Category

Treatment - Surgery

2

Description

Intervention group second: Spine stabilization surgery is performed in 2 stages, first pedicle screws are installed and 6 months after that, the rod and other attachments are installed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital Qom

Full name of responsible person

Dr ali mehrafshan

Street address

Tawheed Square - 9th Street - Tawheed
Physiotherapy Building, 2nd floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr behzad imani

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Parisa hajilo

Position

Master's student in the operating room

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Latest degree

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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

No - There is not 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