

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the results of using peek cage and acrylic cage polymers

Protocol summary

Summary

This single blind clinical trial was aimed to evaluate the clinical and radiographic results of using peek cage and acrylic cage in the patients with cervical discectomy. Sixty-four patients, who had indications of cervical disc surgery and had been treated with discectomy, were randomly allocated to one of two groups. After discectomy was performed, peek cage and acrylic cage were used in the control and study groups, respectively. The patients were followed at 2, 6, and 12 months postoperatively. The patients' clinical improvement was evaluated by the amount of pain reduction and the patients' paraclinical findings were measured by dynamic radiological graphs and CT images which were used to evaluate sagittal angle and amount of subsidence, fusion and subluxation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807132193N3**

Registration date: **2011-06-01, 1390/03/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-06-01, 1390/03/11

Registrant information

Name

Majid Reza Farrokhi

Name of organization / entity

Shiraz Neurosciences Research Center, Shiraz
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz Neurosciences Research Center, Vice-chancellor
for Research Affairs of Shiraz University of Medical
Sciences

Expected recruitment start date

2011-06-02, 1390/03/12

Expected recruitment end date

2012-07-29, 1391/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the results of using peek cage and acrylic
cage polymers

Public title

Evaluation of the results of using peek cage and acrylic
cage in cervical fusion after cervical discectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: indications of cervical disc surgery with
anterior approach Exclusion criteria: history of trauma,
anterior fixation with cervical plate, posterior approach
(Laminectomy), cervical fusion in cases of infection
including brucellae, TB and spinal tumors, severe
osteoporosis, cervical deformity

Age

From **32 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 64

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences

City
Shiraz

Postal code
7194815644

Approval date
2011-05-14, 1390/02/24

Ethics committee reference number
CT-89-5523

Health conditions studied

1

Description of health condition studied
the herniation of intervertebral cervical disc

ICD-10 code
D.21.o

ICD-10 code description
Connective and other soft tissue of head, face and neck

Primary outcomes

1

Description
clinical improvement including cervical pain and radicular pain

Timepoint
Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement
Patient's clinical examination, Patient's history and

performing cervical radiography

Secondary outcomes

1

Description
Evaluation of sagittal angle

Timepoint
Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement
Patient's clinical examination and history, using ODOM'S criterion, dynamic radiographs and CTS based on sagittal index criteria

2

Description
Amount of subsidence of cages

Timepoint
Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement
Clinical examination, the patient's history, using ODOM'S criterion, dynamic radiographs and CTS based on sagittal index criteria.

3

Description
Fusion rate

Timepoint
Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement
Patient's clinical examination and history, using ODOM'S criterion, dynamic radiographs and CTS based on sagittal index criteria

4

Description
Subluxation of cage

Timepoint
Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement
Patient's clinical examination and history, using ODOM'S criterion, dynamic radiographs and CTS based on sagittal index criteria

5

Description
Arthrosis formation in lateral segments

Timepoint
Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement
Patient's clinical examination and history, using ODOM'S criterion, dynamic radiographs and CTS based on sagittal index criteria

6

Description

Possible fracture of cage

Timepoint

Before the operation, 2 and 6 months, 1 and 2 years after the operation

Method of measurement

Patient's clinical examination and history, using ODOM'S criterion, dynamic radiographs and CTS based on sagittal index criteria

Intervention groups

1

Description

Using peek cage in 32 patients as the control group during 1 year.

Category

Treatment - Surgery

2

Description

Using acrylic cage in 32 patients as the intervention group during 1 year.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Dr. Majid Reza Farrokhi

Street address

Shiraz Neurosciences Research Center-Chamran Hospital

City

Shiraz

2

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr. Majid Reza Farrokhi

Street address

Shiraz Neurosciences Research Center-Chamran Hospital

City

Shiraz

3

Recruitment center

Name of recruitment center

Chamran out-patient Clinic

Full name of responsible person

Dr. Majid Reza Farrokhi

Street address

Shiraz Neurosciences Research Center-Chamran Hospital

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4

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Dr. Majid Reza Farrokhi

Street address

Shiraz Neurosciences Research Center-Chamran Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research Affairs of Shiraz University of Medical Sciences

Street address

Vice-chancellor for Research Affairs-Central Building of Shiraz University of Medical Sciences-Zand boulevard-Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz Neurosciences Research Center-Shiraz University of Medical Sciences

Full name of responsible person

Dr. Majid Reza Farrokhi

Position

Neurosurgeon-Fellowship of spinal surgery-Dean of Shiraz Neurosciences Research Center

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Full name of responsible person

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Full name of responsible person

Mahshid Hosseini

Position

The Expert of Research Affairs of the Center

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

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty