# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 perfomed, 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)
**Phone**
+98 71 1623 4508
**Email address**
neuroscien@sums.ac.ir

**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
**City**
Shiraz

**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**
Shiraz

## 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
**Other areas of specialty/work**
**Street address**
Shiraz Neurosciences Research Center-Chamran Hospital
**City**
Shiraz
**Postal code**
7194815644
**Phone**
+98 71 1623 4508
**Fax**
+98 71 1623 4508
**Email**
farokhim@sums.ac.ir,farrokhi_drmr@yahoo.com
**Web page address**
http://www.shiraz-neuroscience.com

## Person responsible for scientific 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**
Neurosergeon-Fellowship of Spinal Surgery
**Other areas of specialty/work**
**Street address**
Shiraz Neurosciences Research Center-Chamran Hospital
**City**
Shiraz
**Postal code**
7194815644
**Phone**
+98 71 1623 4508
**Fax**
+98 71 1623 4508
**Email**
farokhim@sums.ac.ir,farrokhi_drmr@yahoo.com
**Web page address**
http://www.shiraz-neuroscience.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shiraz Neurosciences Research Center-Shiraz University of Medical Sciences
**Full name of responsible person**
Mahshid Hosseini
**Position**
The Expert of Research Affairs of the Center
**Other areas of specialty/work**
**Street address**
Shiraz Neurosciences Research Center-Chamran Hospital
**City**
Shiraz
**Postal code**
7194815644
**Phone**
+98 71 1623 4508
**Fax**
+98 71 1623 4508
**Email**
neuroscien@sums.ac.ir, hosseini_2m@yahoo.com
**Web page address**
http://www.shiraz-neuroscience.com

## 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*