

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

A comparative study on surgical outcome between limited discectomy and aggressive discectomy method

Protocol summary

Study aim

Comparison of two surgical methods, limited and aggressive

Design

Two arm parallel group randomized trial (each group 40 patients) with two different type of surgery with blinded collecting and analyzing process

Settings and conduct

Patients were selected between admitted ones in neurosurgery ward of Arak's valiasr hospital and correlated outcomes with blinded data collector and analizer (without knowledge about the type of surgery on patients) were collected one day before and a day and six month after surgery

Participants/Inclusion and exclusion criteria

age under 60, single level disc herniation, no diabetes, no heavy smoking

Intervention groups

first group: limited discectomy with just sequestrectomy and removing pressure on nerve root second group: maximal effort to evacuate disc space after pressure removal on nerve root

Main outcome variables

pain score a day before surgery pain score a day after surgery pain score, discitis, steomyelitis and recurrent disc herniation during 6 months after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043261N1**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Alireza Lotfipour fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7745 2311

Email address

alireza.lotfipour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2019-03-19, 1397/12/28

Scientific title

A comparative study on surgical outcome between limited discectomy and aggressive discectomy method

Public title

Role of type of discectomy surgey in patients outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single level disc herniation

Exclusion criteria:

Diabetes mellitus Heavy smokers age over 60

Age

To 60 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Actual sample size reached: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random patient's admission dates

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants, clinical observer and researcher, data collector and analyser didn't know about the type of procedure that was done on patient

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Arak University of Medical Sciences

Street address

No. 156, Block 1, Baharan complex, Shahid Kazemi st, Hangam st.

City

Tehran

Province

Tehran

Postal code

1677733141

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

ir.arakmu.rec.1397.252

Health conditions studied**1****Description of health condition studied**

lumbar disc herniation

ICD-10 code

M51.3

ICD-10 code description

Other thoracic, thoracolumbar and lumbosacral intervertebral disc degeneration

Primary outcomes**1****Description**

Patient pain score

Timepoint

a day before and after surgery, and during 6 month after surgery

Method of measurement

pain by VAS score

2**Description**

Recurrent disc herniation

Timepoint

During 6 months after surgery

Method of measurement

Recurrent signs and symptoms of the patient and radiologic evidences on MRI

3**Description**

Discitis and steomyelitis

Timepoint

During 6 months after surgery

Method of measurement

Patient's signs and symptoms, lab datas (WBC, ESR and CRP), Evidences on MRI

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: patients with lumbar disc herniation that needs surgery treated with limited discectomy method

Category

Treatment - Surgery

2**Description**

Intervention group: Intervention group: patients with lumbar disc herniation that needs surgery treated with aggressive discectomy method

Category

Treatment - Surgery

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital of Arak city, Iran

Full name of responsible person

Alireza Lotfipour Fard

Street address

Valiasr sq

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Alamolhoda st, Shiroudi st

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 6055

Email

info@arakmu.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

2**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Lotfipour

Street address

Valiasr hospital, Valiasr sq, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

alireza.lotfipour@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Researcher

Proportion provided by this source

90

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Lotfipour

Position

neurosurgery assistant

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

No 156, Block 1, Baharan Complex, shahid Kazemi St, Hangam St,

City

Tehran

Province

Tehran

Postal code
1677733141
Phone
+98 21 7745 3221
Email
alireza.lotfipour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Lotfipour
Position
neurosurgery assistant
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
No 156, Block 1, Baharan Complex, shahid Kazemi St,
Hangam St,
City
Tehran
Province
Tehran
Postal code
1677733141
Phone
+98 21 7745 3221
Email
alireza.lotfipour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Lotfipour
Position
neurosurgery resident
Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery
Street address
No 156, Block 1, Baharan Complex, shahid Kazemi St,
Hangam St,
City
Tehran
Province
Tehran
Postal code
1677733141
Phone
+98 21 7745 3221
Email
alireza.lotfipour@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The database is available in an EXCEL file

When the data will become available and for how long

2019 august

To whom data/document is available

everybody

Under which criteria data/document could be used

for further studies with no condition

From where data/document is obtainable

email: alireza.lotfipour@gmail.com

What processes are involved for a request to access data/document

send a request to my e-mail

Comments