Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of macroscopic and microscopic surgical methods in patients undergoing anterior cervical discectomy

Protocol summary

Study aim

Comparison of macroscopic and microscopic surgical procedures in patients undergoing anterior cervical discectomy In Besat Hospital of Hamadan from 1399 to 1400

Design

A clinical trial with a control group, with parallel groups, singe blinded, randomized phase 3 on 60 patients, Rand function of Excel software will be used for randomization.

Settings and conduct

The study will be conducted on patients with cervical discopathy under the age of 70 years old in Besat Hospita in Hamadan. Patients who are eligible to enter the study will be randomly assigned to two intervention groups A and B. Group A will undergo cervical discectomy surgery by macroscopic method and group B will undergo cervical discectomy surgery by microscopic method. In this study, the person who assesses the surgical outcomes will be blinded of the surgical method used (single blind).

Participants/Inclusion and exclusion criteria

inclusion criteria: suffering from non-traumatic cervical discopathy, the number of discopathy levels less than three levels and conditions for not entering the study: age over 70 years, presence of calcification of the posterior ligament

Intervention groups

One group of patients will undergo cervical discectomy surgery by macroscopic method and another group will undergo cervical discectomy surgery by microscopic method.

Main outcome variables

The main outcomes of the study are: pain severity, amount of analgesic and narcotic drugs need, dysphagia complications, septicemia, bleeding during and after the operation, length of hospital stay.

General information

Reason for update

Acronym

دیسکتومی

IRCT registration information

IRCT registration number: **IRCT20151123025202N27**
Registration date: **2023-01-02, 1401/10/12**
Registration timing: **prospective**

Last update: **2023-01-02, 1401/10/12**
Update count: **0**

Registration date

2023-01-02, 1401/10/12

Registrant information

Name
Abbas Moradi
Name of organization / entity
Hamedan University of Medical Of Science
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 0097
Email address
a.moradi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of macroscopic and microscopic surgical methods in patients undergoing anterior cervical discectomy

Public title
Cervical disc surgery by macroscopic and microscopic methods

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Non-traumatic cervical discopathy Discopathy less than three levels

Exclusion criteria:
Presence of posterior ligament calcification Age > 70 years

Age
To **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
We made 60 cards and write letters MA on 30 for macroscopy and on the other 30 letters MI for the microscopy group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, randomly select one of the envelopes and open it, based on selected letter (MA or MI) patients assign it to the macroscopy or microscopy discectomy .

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who will assess the pain score and other outcomes of the surgery will be blinded of the surgical procedure

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science

Street address
shahid fahmideh avenue

City
Hamadan

Province
Hamadan

Postal code
6517789971

Approval date
2022-12-03, 1401/09/12

Ethics committee reference number
IR.UMSHA.REC.1401.747

Health conditions studied

1

Description of health condition studied
cervical disc

ICD-10 code
M50

ICD-10 code description
Cervical disc disorders

Primary outcomes

1

Description
pain severity change

Timepoint
24 4 hours after surgery

Method of measurement
Neck pain Visual Analog Scale (NP-VAS)

2

Description
Analgesic consumption

Timepoint
during 24 hours postoperative

Method of measurement
Extract from the patient's medical record

3

Description
Complications of bleeding, septicemia, dysphagia

Timepoint
During the operation and up to 24 hours after the operation

Method of measurement
Surgeon's report, clinical examination and review of patients' medical records

Secondary outcomes

1

Description
Hospitalization period

Timepoint

at discharge time

Method of measurement

Interval time between hospitalization and discharge

Intervention groups

1

Description

Intervention group: They will undergo macroscopic surgery.In the macroscopic method, the cervical spine is accessed through the front. The skin and platysma muscle will be opened and the vertebral column is accessed from the space between the sternocleidomastoid on the side and the mid-cervical structures (trachea and esophagus) in the middle. In this method, the entire injured disc and the osteophytes will be removed, and a bone graft is placed in the space of the removed disc.

Category

Treatment - Surgery

2

Description

Control group: They will undergo microscopic surgery. In this procedure, first, a small incision is made at the back of the neck (midline). By removing the muscle, access to the desired vertebra will be provided. In order to ensure the exact location of the surgery, an X-ray is performed before removing the disc. Then, in order to determine the root of the nerve, a part of the facet joint is removed, finally, using a microscope, the disc under the root is identified and the herniated disc is removed. The nerve root will be returned. The muscles will move back and the incision will be sutured.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital

Full name of responsible person
Mahdi Arjipour

Street address
Shahid Beheshti Blv

City
Hamadan

Province
Hamadan

Postal code
6514845411

Phone
+98 81 3264 0020

Email
besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza Shokohi

Street address
Shahid Fahmide Ave

City
Hamadan

Province
Hamadan

Postal code
6517838677

Phone
+98 81 3838 0717

Fax
+98 81 3838 0130

Email
vc_research@umsha.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

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
Abbas Moradi

Position
Coach

Latest degree
Master

Other areas of specialty/work
Epidemiology

Street address
Shahid fahmideh street Medical school

City
Hamadan

Province
Hamadan

Postal code
6517838736
Phone
+98 81 3838 0097
Fax
+98 81 3838 0208
Email
a.moradi@umsha.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mahdi Arjipour
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Hamedan shahid fahmideh street medicine school
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0572
Fax
+98 81 3838 0208
Email
m.arjipour@umsha.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
Coach
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Shahid fahmideh street medicine school
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0097
Fax
+98 81 3838 0208
Email
a.moradi@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
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