

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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, single 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 University 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

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6514845411

##### Phone

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##### 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

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##### Province

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##### 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

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Shahid fahmideh street Medical school

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## Person responsible for scientific inquiries

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Associate professor  
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## Person responsible for updating data

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## 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