

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Efficacy of Non-instrumented Versus Instrumented Fusion in Anterior Cervical Discectomy

Protocol summary

Study aim

As very few studies were conducted in our region on this topic this study designed to assess role of instrumented and non-instrumented decompression of cervical spine disorders and to compare these modalities in terms of pain relief and recovery time with little more complication rate.

Design

Two-arm parallel group, single-blind randomised controlled trial. Randomisation is manual with lottery method using the concealed envelopes. Randomisation sequence carried out at an external site before the procedure, after explaining the details of study and informed consent.

Settings and conduct

Department of Neurosurgery, Gambat Institute of Medical Sciences, Gambat, Pakistan from May 2023 to May 2024,

Participants/Inclusion and exclusion criteria

Patients of degenerative cervical disease were enrolled and detailed clinical examination and complete history of any previous medical illness and surgical interventions was obtained. Patients with failed conservative management plan, developed neurological deficits were included and patients with history of any cardiac disease, cervical radiculopathy from below 12 weeks, two level disease, neurological deficit of advance stage, diabetic patients with neuropathy, and unfit for general anesthesia were excluded.

Intervention groups

1) Anterior cervical discectomy (ACD) 2) Anterior cervical discectomy and fusion (ACDF)

Main outcome variables

Pain reduction, recovery rate, and complications in cervical degenerative diseases.

General information

Reason for update

Acronym

ACDF-NI

IRCT registration information

IRCT registration number: **IRCT20241220064110N1**

Registration date: **2025-01-16, 1403/10/27**

Registration timing: **retrospective**

Last update: **2025-01-16, 1403/10/27**

Update count: **0**

Registration date

2025-01-16, 1403/10/27

Registrant information

Name

Tahir Shahab

Name of organization / entity

Gambat Institute of Medical Sciences Gambat, Pakistan

Country

Pakistan

Phone

+92 332 2358385

Email address

dr.tahirshahab@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-01, 1402/02/11

Expected recruitment end date

2024-05-01, 1403/02/12

Actual recruitment start date

2023-05-01, 1402/02/11

Actual recruitment end date

2024-05-01, 1403/02/12

Trial completion date

2024-10-01, 1403/07/10

Scientific title

Comparing the Efficacy of Non-instrumented Versus Instrumented Fusion in Anterior Cervical Discectomy

Public title

Efficacy of Non-instrumented Versus Instrumented Fusion in Anterior Cervical Discectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18-65 years of both genders
Patients of degenerative cervical disease
Patients with failed conservative management plan
Patients who developed neurological deficits

Exclusion criteria:

Patients with a history of any cardiac disease
Cervical radiculopathy from below 12 weeks
Patients with two-level disease
Patients who developed neurological deficits of advanced stage
Diabetic patients with neuropathy,
Patients unfit for general anesthesia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization based on individual unit was done using a lottery method in a concealed envelop, mentioning the name of intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

in this study, the only participants of study i.e patients were blinded only regarding which type of intervention they will receives. The investigators and care takers were fully aware about the intervention groups and provided upto the mark care.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Ethical Review Board, Gambat

Street address

Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences, Gambat Station Road, Pakistan

City

Gambat

Postal code

66080

Approval date

2023-04-01, 1402/01/12

Ethics committee reference number

PAQSJIMS/GMC/ORIC/07

Health conditions studied

1

Description of health condition studied

Degenerative cervical disease

ICD-10 code

M50.30

ICD-10 code description

Other cervical disc degeneration, unspecified cervical region

Primary outcomes

1

Description

Pain Reduction

Timepoint

12 weeks after the intervention

Method of measurement

VAS score for pain

2

Description

Recovery Rate

Timepoint

12 weeks after the intervention

Method of measurement

Time of recovery

Secondary outcomes

1

Description

Length of hospital stay

Timepoint

hospital stay

Method of measurement

days of hospital stay

Intervention groups

1

Description

Anterior Cervical Dissectomy and fusion will serve as the Intervention group. After induction under general anesthesia, in a supine position, a layer-by-layer blunt dissection will be performed. Dissectomy was performed with loupe magnification to achieve precise surgical intervention. During surgery in cases of hypertrophy and OPLL posterior longitudinal ligament and dura matter were severed, foramina patency was assessed and stenosis was relieved with foraminotomy. Bone graft was placed with graft cage and anterior interlocking was done at specific positions. Plate positioning and sagittal alignment were confirmed intraoperatively using fluoroscopy.

Category

Treatment - Devices

2

Description

Anterior Cervical Dissectomy will serve as the Control group: After induction under general anesthesia, in a supine position, a layer-by-layer blunt dissection will be performed. Only Dissectomy will be performed with loupe magnification to achieve precise surgical intervention

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences Gambat

Full name of responsible person

Tahir Shahab

Street address

Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences, Gambat Station Road, Pakistan

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Email

dr.tahirshahab@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neurosurgery Department, Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences Gambat,

Full name of responsible person

Tahir Shahab

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Neurosurgery Department, Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences Gambat,

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

Neurosurgery Department, Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences Gambat,

Full name of responsible person

Tahir Shahab

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Jeelani Institute of Medical Sciences Gambat,

Full name of responsible person

Tahir Shahab

Position

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Comparing the efficacy of non-instrumented versus
instrumented fusion in anterior cervical discectomy; as
soon as the study is completed, there is plan to a share
the document as well as data

**When the data will become available and for how
long**

Data will be available publicly forever

To whom data/document is available

To all the medical fraternity

Under which criteria data/document could be used

document can be used for similar studies, esp carrying
out meta-analysis

From where data/document is obtainable

Data will be shared on demand via email, as well as from
the publishers site

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

Just a simple email will be required.

Comments

Comparing the efficacy of non-instrumented versus
instrumented fusion in anterior cervical discectomy, this
work has been done with great responsibility, dedication,
and honesty. It will be a rich source of decision-making
for neurosurgeons.