

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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		Institutional Ethical Review Board, Gambat	
Public title		Street address	
Efficacy of Non-instrumented Versus Instrumented Fusion in Anterior Cervical Discectomy		Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences, Gambat Station Road, Pakistan	
Purpose		City	
Treatment		Gambat	
Inclusion/Exclusion criteria		Postal code	
Inclusion criteria:		66080	
Patients aged 18-65 years of both genders Patients of degenerative cervical disease Patients with failed conservative management plan Patients who developed neurological deficits		Approval date	
Exclusion criteria:		2023-04-01, 1402/01/12	
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		Ethics committee reference number	
Age		PAQSJIMS/GMC/ORIC/07	
From 18 years old to 65 years old		Health conditions studied	
Gender		<u>1</u>	
Both		Description of health condition studied	
Phase		Degenerative cervical disease	
2-3		ICD-10 code	
Groups that have been masked		M50.30	
Participant		ICD-10 code description	
Sample size		Other cervical disc degeneration, unspecified cervical region	
Target sample size: 48		Primary outcomes	
Actual sample size reached: 52		<u>1</u>	
Randomization (investigator's opinion)		Description	
Randomized		Pain Reduction	
Randomization description		Timepoint	
simple randomization based on individual unit was done using a lottery method in a concealed envelop, mentioning the name of intervention group.		12 weeks after the intervention	
Blinding (investigator's opinion)		Method of measurement	
Single blinded		VAS score for pain	
Blinding description		<u>2</u>	
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.		Description	
Placebo		Recovery Rate	
Not used		Timepoint	
Assignment		12 weeks after the intervention	
Parallel		Method of measurement	
Other design features		Time of recovery	
Secondary Ids		Secondary outcomes	
empty		<u>1</u>	
Ethics committees		Description	
<u>1</u>		Length of hospital stay	
Ethics committee		Timepoint	
Name of ethics committee		hospital stay	
		Method of measurement	
		days of hospital stay	
		Intervention groups	
		<u>1</u>	
		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

City

Gambat

Postal code

66080

Phone

+92 332 2358385

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

Pir Abdul Qadir Shah Jeelani Institute of Medical

Sciences, Gambat Station Road, Pakistan

City

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66080

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

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Province

Sindh

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66080

Phone

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Email

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

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

Full name of responsible person

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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 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.