Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 envelops. 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

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+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 postion, a layer-by-layer blunt dissection will be performed. Discectomy 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 postion, a layer-by-layer blunt dissection will be performed. Only Discectomy 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

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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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Position
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Person responsible for updating data

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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.