Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Formulation and evaluation of methylcobalamin gel with and without Phonophoresis and mulligan traction & mobilization in Cervical Radiculopathy

Protocol summary

Study aim
Evaluates the effectiveness of Mulligan techniques in reducing pain and improving mobility, strength, and function in cervical radiculopathy patients, with and without methylcobalamin. It also examines whether combining Mulligan techniques with methylcobalamin enhances nerve function recovery.

Design
A comparative study with sample size 370, Randomly allocate the subjects into two groups. Intervention &control group

Settings and conduct
Muhammad physical therapy clinic and rehabilitation center, Multan

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18–70y Uni-lateral upper-extremity pain, paresthesia, or numbness Loss of reflexes in the affected nerve root distribution Motor or sensory dysfunction (optional) Pain radiating to the arm cervical rotation range of motion less than 60 degrees Positive distraction test Positive Spurling's Exclusion criteria: Fractures Open wounds Patients with spinal cord compression Traumatic injuries Cancer

Intervention groups
Patients will receive Mulligan traction and mobilization with methylcobalamin via phonophoresis for 12 sessions over 4 weeks (3 times per week). Manual traction will last 10 minutes (10 sec pull, 5 sec rest), and phonophoresis will be applied for 5-7 minutes per session using 0.8 MHz frequency, 1.5 W/cm² intensity, and continuous 2:1 mode.

Main outcome variables
Immediate pain relief, improved mobility, and long-term nerve regeneration, reducing inflammation and promoting muscle and sensory recovery.

General information

Reason for update
Data missing

Acronym

IRCT registration information
IRCT registration number: **IRCT20241220064105N2**
Registration date: **2025-01-17, 1403/10/28**
Registration timing: **prospective**

Last update: **2025-02-21, 1403/12/03**
Update count: **1**

Registration date
2025-01-17, 1403/10/28

Registrant information

Name
Komal Ammar Bukhari

Name of organization / entity
Muhammad Institute of Medical Sciences, Multan

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-25, 1403/11/06

Expected recruitment end date
2025-04-25, 1404/02/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Formulation and evaluation of methylcobalamin gel with and without Phonophoresis and mulligan traction & mobilization in Cervical Radiculopathy

Public title
methylcobalamin gel with and without Phonophoresis and mulligan traction & mobilization in Cervical Radiculopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18–70y Uni-lateral upper-extremity pain, paresthesia, or numbness loss of reflexes in the affected nerve root distribution Motor or sensory dysfunction (optional) Pain radiating to the arm cervical rotation range of motion less than 60 degrees Positive distraction test Positive Spurling's

Exclusion criteria:
Fractures Open wounds Patients with spinal cord compression Traumatic injuries Cancer

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **370**

Randomization (investigator's opinion)
Randomized

Randomization description
This randomization will be done by Lottery method to ensure fairness. Medications will be given in numbered white boxes, each with a unique medication number. The treatment codes will be kept by the principal investigator.

Blinding (investigator's opinion)
Double blinded

Blinding description
"The statistical analyst and outcome assessor will be blinded to treatment allocation by using securely stored randomization codes, accessible only to an independent party. Data will be analyzed using anonymous identifiers, and group allocation will be revealed only after data collection and analysis are complete. This ensures minimization of bias.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences

Street address
Bosan Road

City
Multan

Postal code
66000

Approval date
2024-12-20, 1403/09/30

Ethics committee reference number
MIMAS/01/8/Komal

Health conditions studied

1

Description of health condition studied
Cervical Radiculopathy

ICD-10 code
M50.1

ICD-10 code description
Cervical disc disorder with radiculopathy

Primary outcomes

1

Description
Pain

Timepoint
4-week

Method of measurement
NPRS

2

Description
Cervical Radiculopathy disorder

Timepoint
4-weeks

Method of measurement
NDI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will be treated with Mulligan traction and mobilization with methylcobalamin via phonophoresis. Manual traction will be given for 10 minutes with a pull for 10 sec and rest will be 5 sec. The duration of three treatment sessions (10-20 minutes) per week for 4-weeks, consisting of 12 treatment sessions in total. Methylcobalamin with Phonophoresis is commonly used with a frequency of about 0.8 MHz, intensity 1.5 W/cm2, and continuous mode 2:1. Methylcobalamin with phonophoresis will be applied for a 4-weeks period, 3 times per week and each session lasted for about5-7 minutes

Category
Rehabilitation

2

Description
Control group: will be treated with Mulligan traction and mobilization, Mulligan Manual traction will be given for 10 minutes with a pull for 10 sec and rest will be 5 sec. The duration of three treatment sessions (10-20 minutes) per week for four weeks, consisting of 12 treatment sessions in total. Mulligan SMWAM will be given to only patients by maintaining transverse glide with 10 repetitions in the first session increasing to 30 repetitions with the sets of 3 in further sessions. Subjects will be given Mulligan mobilizations (SNAGs). The duration of three treatment sessions (10-20 minutes) per week for four weeks, consisting of 12 treatment sessions in total.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Muhammad physical therapy & rehabilitation center Multan

Full name of responsible person
Maliha Khalid Khan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Muhammad Instituite of Rehabilitation Sciences, Multan

Full name of responsible person
Qurat ul Ain

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Grant name
Student

Grant code / Reference number
MIMAS/2/6/Iqra

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

Title of funding source
Muhammad Instituite of Rehabilitation Sciences, Multan

Proportion provided by this source
70

Public or private sector
Private

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
Muhammad Instituite of Medical and Allied Sciences, Multan

Full name of responsible person
Maliha Khalid Khan

Position
Lecturer

Latest degree
Medical doctor

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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