

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Pakistan

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+92 314 6361728

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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 about 5-7 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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Bosan Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Muhammad Institute 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/lqra

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

Yes

Title of funding source

Muhammad Institute 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 Institute 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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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