

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Evaluation of Amplitude, Velocity and Latency Period of Sensory Nerve Action Potential of Proximal Part of Medial Branch of Superficial Radial Nerve for Diagnosis of Cheiralgia Paresthetica in Patients vs Control: A Randomized Control Trial

#### Protocol summary

##### Study aim

To assess whether Amplitude, velocity and latency period of Proximal part of Medial Branch of Superficial Radial Nerve can be utilized clinically for diagnosis of cheiralgia paresthetica or not?

##### Design

Parallel group, double blind, randomised controlled trial

##### Settings and conduct

Out patient department (OPD) of PM&R Department of Combined Military Hospital Multan. Patients, Investigators, data entry staff, analyzers and statistician were blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Intervention Group: All individuals with symptoms of peripheral neuropathy of superficial radial nerve. Control Group: All individuals without symptoms of peripheral neuropathy of superficial radial nerve. Exclusion criteria All individuals with history of stroke, diabetes mellitus, hypertension, brachial plexus plexopathy, cervical radiculopathy, spinal cord injury.

##### Intervention groups

Nerve conduction study (NCS) of proximal part of medial branch of superficial radial nerve of intervention and control group and calculating: 1. Amplitude of Sensory nerve action potential (SNAP) 2. Latency of Nerve Action Potential 3. Velocity of Nerve Action Potential

##### Main outcome variables

Amplitude, Velocity and Latency period of Sensory Nerve Action Potential (SNAP)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200814048399N1**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

##### Registration date

2020-09-01, 1399/06/11

##### Registrant information

###### Name

Muhammad Tawab Khalil

###### Name of organization / entity

Armed Forces Institute of Rehabilitation Medicine

###### Country

Pakistan

###### Phone

+92 51 5418692

###### Email address

tawabkhalil2013@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-10, 1399/07/19

##### Expected recruitment end date

2021-02-28, 1399/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Amplitude, Velocity and Latency Period of Sensory Nerve Action Potential of Proximal Part of Medial

Branch of Superficial Radial Nerve for Diagnosis of Cheiralgia Paresthetica in Patients vs Control: A Randomized Control Trial

## Public title

Evaluation of Amplitude, Velocity and Latency Period of Sensory Nerve Action Potential of Proximal Part of Medial Branch of Superficial Radial Nerve for Diagnosis of Cheiralgia Paresthetica in Patients vs Control: A Randomized Control Trial

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

Intervention Group: All individuals with symptoms of peripheral neuropathy of superficial radial nerve  
Control Group: All individuals without symptoms of peripheral neuropathy of superficial radial nerve.

### Exclusion criteria:

All individuals with history of stroke, diabetes mellitus, hypertension, brachial plexus plexopathy, cervical radiculopathy, spinal cord injury.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: 26

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients with abnormal and normal sensation on dorsum of the hand will be de-identified at the reception counter and will be given randomly generated numbers by the help of website (<https://www.random.org/>) in place of their names by the receptionist. They EMG / NCS will then be performed on these patients by a physician and Amplitude Velocity and Latency period of Sensory Nerve Action Potential (SNAP) will be written by hand on a separate paper with out mentioning the name or diagnosis of patient and enclosed in the envelop with number of patient mentioned outside the envelop. The reports of EMG/NCS will then be segregated into two groups viz Group-I (patients with abnormal sensation) and Group-II (Control) by a separate staff member. The data of patients in each group will then be uploaded by another staff member on SPSS who do not know which group is control and which is intervention group. After that, data sheet will then be analysed by separate statistician who will not be informed regarding which group is control and which is intervention group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

CMH Multan Ethical Review Committee

##### Street address

Combined Military Hospital Multan

##### City

Multan

##### Postal code

66000

#### Approval date

2020-06-08, 1399/03/19

#### Ethics committee reference number

cmh/erc/00161

## Health conditions studied

### 1

#### Description of health condition studied

Cheiralgia Paresthetica

#### ICD-10 code

G56.30

#### ICD-10 code description

Lesion of radial nerve, unspecified upper limb

## Primary outcomes

### 1

#### Description

Amplitude, Velocity and Latency period of Sensory Nerve Action Potential (SNAP)

#### Timepoint

At the time of recruitment

#### Method of measurement

Nerve Conduction Study of Proximal part of Medial branch of SRN will be done anti-dromically on the affected side of participants of group-I and on both sides of participants of group-II. Stimulation electrodes will be applied 10 cm proximal to radial styloid. Recording electrode will be placed at Anatomical snuff box while Reference electrode will be place at first metacarpophalangeal joint. Amplitude, Latency and Velocity of Sensory Nerve Action Potential(SNAP) will be recorded.

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group:

### Category

Diagnosis

2

### Description

Control group:

### Category

Diagnosis

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Combined Military Hospital Multan

#### Full name of responsible person

Muhammad Tawab Khalil

#### Street address

Combined Military Hospital Multan

#### City

Multan

#### Postal code

66000

#### Phone

+92 51 5418692

#### Email

tawabkhalil2013@gmail

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Combined Military Hospital Multan

#### Full name of responsible person

Ali Raza Qureshi

#### Street address

Combined Military Hospital Multan

#### City

Multan

#### Postal code

66000

#### Phone

+92 51 5418692

#### Email

tawabkhalil2013@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

No

### Title of funding source

Combined Military Hospital Multan

### Proportion provided by this source

1

### 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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Armed Forces of Rehabilitation Medicine, Rawalpindi

#### Full name of responsible person

Muhammad Tawab Khalil

#### Position

Resident Physician

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Physical Medicine and Rehabilitation

#### Street address

AFIRM, Rawalpindi

#### City

Rawalpindi

#### Province

Punjab

#### Postal code

4600

#### Phone

+92 51 5418692

#### Email

tawabkhalil2013@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Armed Forces Institute of Rehabilitation Medicine

#### Full name of responsible person

Muhammad Tawab Khalil

#### Position

Doctor

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Physical Medicine and Rehabilitation

#### Street address

Rawalpindi Cantonment

#### City

Rawalpindi

#### Province

Punjab

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46000

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**Person responsible for updating data****Contact****Name of organization / entity**

Armed Forces Institute of Rehabilitation Medicine

**Full name of responsible person**

Muhammad Tawab Khalil

**Position**

Doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine and Rehabilitation

**Street address**

Rawalpindi Cantonment

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 51 5418692

**Fax****Email**

tawabkhalil2013@gmail.com

**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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Individual participant data that underlie the results reported in this article after de-identification will be shared beginning 3 months and ending 5 years following article publication with researchers who provide a methodologically sound proposal to achieve the aims mentioned in the approved proposal. Proposals should be sent to tawabkhalil2013@gmail.com. To gain access data requestors will need to sign data access agreement.

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

Beginning 3 months and ending 5 years following article publication with researchers who provide a methodologically sound proposal to achieve the aims mentioned in the approved proposal.

**To whom data/document is available**

Researchers who provide a methodologically sound proposal to achieve the aims mentioned in the approved proposal.

**Under which criteria data/document could be used**

For personal use only.

**From where data/document is obtainable**

Proposals of request to access the data should be sent to tawabkhalil2013@gmail.com. To gain access data requestors will need to sign data access agreement.

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

Proposals of request to access the data should be sent to tawabkhalil2013@gmail.com. To gain access data requestors will need to sign data access agreement.

**Comments**