

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Therapeutic Outcomes Of Dry Needling Coupled With Intramuscular Stimulation In Patients With Fibromyalgia Syndrome

Protocol summary

Study aim

To evaluate the therapeutic outcomes of dry needling coupled with intramuscular stimulation in patients with fibromyalgia syndrome.

Design

A concealed, randomized, blinded, controlled trial with a parallel group design of 78 patients

Settings and conduct

Physical Therapy Department, University of Lahore Teaching Hospital, Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria Both male and female patients; Age over 18 years and under 60 years; Pre diagnosed patients with FMS referred through consultant; Manifesting chronic widespread musculoskeletal pain symptoms; Presence of active trigger points, as confirmed by physical examination; No contraindications to dry needling or IMS. Exclusion Criteria Pregnancy or breastfeeding; Use of any medications that could interfere with the study results e.g. muscle relaxants, opioids within the past 48 hours; Previous treatment with dry needling or IMS within the past 6 months; Presence of any other conditions that could interfere with the study results e.g. cancer, infection;

Intervention groups

Group A: This group will be given dry needling and conventional treatment. The sterile stainless steel 0.25*25mm to 0.25*50mm (Hua long) acupuncture needle will be inserted. CPT will consist of Application of hot pack for 10 minutes, TENS (typical, 100 Hz) for 20 mins at the affected region. Isometric exercise, Range of Motion, Stretching and strengthening exercise of affected region. Therapy will be provided for one session per week for four weeks. Group B: This group will be given dry needling and IMS will be applied for 15 minutes (low frequency parameters (2 Hz) and a pulse width of 120 µs). Conventional physical therapy will be given as of Group A.

Main outcome variables

Numeric Pain Rating Scale; Pain pressure threshold; algometer; Quality of sleep; Anxiety depression; Fatigue scale

General information

Reason for update

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20240125060803N1**

Registration date: **2024-06-01, 1403/03/12**

Registration timing: **prospective**

Last update: **2024-06-01, 1403/03/12**

Update count: **0**

Registration date

2024-06-01, 1403/03/12

Registrant information

Name

Muhammad Asim Arif

Name of organization / entity

University of Lahore

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-10, 1403/03/21

Expected recruitment end date

2025-12-10, 1404/09/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Therapeutic Outcomes Of Dry Needling Coupled With Intramuscular Stimulation In Patients With Fibromyalgia Syndrome

Public title
Therapeutic Outcomes Of Dry Needling Coupled With Intramuscular Stimulation In Patients With Fibromyalgia Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Both male and female patients Age over 18 years and under 60 years Pre diagnosed patients with FMS referred through consultant Manifesting chronic widespread musculoskeletal pain symptoms Presence of active trigger points, as confirmed by physical examination Willing and able to provide informed consent to participate in the study. Ability to understand and comply with the study requirements No contraindications to dry needling or IMS

Exclusion criteria:
Pregnancy or breastfeeding Use of any medications that could interfere with the study results (e.g. muscle relaxants, opioids) within the past 48 hours. Previous treatment with dry needling or IMS within the past 6 months Presence of any other conditions that could interfere with the study results (e.g. cancer, infection) Participation in any other clinical trials within the past 30 days Anatomical anomaly Structural disorder of spinal alignment (Scoliosis, kyphosis, lordosis) o Any bone abnormality in neck region Traumatic/ Inflammatory/ Infectious Conditions such as Recent Trauma, Nerve root compromise, Metabolic or serious spinal pathologies (e.g., fractures, tumors, inflammatory, and infectious diseases), Previous neck surgery Psycho-social Instability such as Diagnosed stress/ depression/ Anxiety Risk Profile such as High Risk Inability to understand or comply with the study requirements, as determined by the physiotherapist

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Computerized method of randomization will be used to

randomized screened eligible patients to Group A and B. OxMaR will be used for this purpose, which is an open source free software for online minimization and randomization for clinical trials

Blinding (investigator's opinion)
Single blinded

Blinding description
It will be single blinded, only the assessor would be managed to be masked from treatment options and outcomes. Ultimately, the decision about which type of blinding to use in a clinical trial will depend on the specific research question being addressed, the nature of the treatments being compared, and the resources and logistics of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethical committee

Street address
1-Km Defence Road, Off Bhoptian Chowk, Raiwind Road, Lahore

City
lahore

Postal code
54000

Approval date
2024-05-22, 1403/03/02

Ethics committee reference number
REC-UOL-/183/08/24

Health conditions studied

1

Description of health condition studied
Fibromyalgia Syndrome

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Pain

Timepoint
Baseline screening, Assessment at 2nd week interval,

Assessment at 4th week interval, Follow up at 8th week interval

Method of measurement

Numeric Pain Rating Scale

2

Description

Pressure

Timepoint

Baseline screening, Assessment at 2nd week interval, Assessment at 4th week interval, Follow up at 8th week interval

Method of measurement

Pain pressure threshold; algometer

3

Description

Anxiety depression

Timepoint

Baseline screening, Assessment at 2nd week interval, Assessment at 4th week interval, Follow up at 8th week interval

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

4

Description

Quality of Sleep

Timepoint

Baseline screening, Assessment at 2nd week interval, Assessment at 4th week interval, Follow up at 8th week interval

Method of measurement

Pittsburgh Sleep Quality Index (PSQI).

5

Description

Fatigue

Timepoint

Baseline screening, Assessment at 2nd week interval, Assessment at 4th week interval, Follow up at 8th week interval

Method of measurement

Multidimensional Fatigue Inventory (MFI).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dry Needling With Intramuscular Electrical Stimulation

Category

Treatment - Other

2

Description

Control group: Dry Needling Group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Department, University of Lahore Teaching Hospital, Lahore

Full name of responsible person

Rabia Saeed

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1-km defence road off bhoptian chowk, raiwind road, lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of lahore

Full name of responsible person

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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

The university of lahore

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Academic

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

The University of Lahore

Full name of responsible person

Muhammad Asim Arif

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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

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Latest degree

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Other areas of specialty/work

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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

No - There is not 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