Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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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