

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Diclofenac Potassium Gel with and without Transcutaneous Electrical Nerve Stimulation in Primary Dysmenorrhea

Protocol summary

Study aim

This study aims to formulate a topical diclofenac potassium gel and evaluate its effectiveness in managing primary dysmenorrhea. It also seeks to compare the pain-relieving effects of the gel alone versus in combination with Transcutaneous Electrical Nerve Stimulation (TENS) to determine the potential benefit of combined therapy.

Design

Pragmatic, community based, parallel group, double blinded, randomized controlled trial. Total 376 patients will be enrolled. Patients who met our inclusion criteria will be randomized into two groups.

Settings and conduct

The trial will be held at Muhammad Physical Therapy & Rehabilitation Center, Multan. It is single-blinded, with participants unaware of their group. Treatments will be in identical boxes, and codes kept by the principal investigator.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Woman (18-45 years), Female diagnosed with primary or secondary dysmenorrhea, Regular menstrual cycles (21-35days), Females, Moderate to severe menstrual pain, Intervention was physiotherapy techniques (electro-physical agents, massage, exercise). Exclusion Criteria Pregnancy Females with bleeding disorders, Breast feeding, Uterine fibroids, Adenomyosis, Endometriosis, Pelvic inflammatory disease, Menstrual disorder

Intervention groups

Group A will receive 6% diclofenac potassium gel plus TENS, while Group B will use the gel alone. Both groups will apply 2-4 grams of gel 2-4 times daily for up to three days. Group A will also get Transcutaneous Electrical Nerve Stimulation (80-100 Hz, 20-30 minutes, 2-3 times daily) to enhance pain relief.

Main outcome variables

range of motion, joint stiffness, independency and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241220064105N4**

Registration date: **2025-06-02, 1404/03/12**

Registration timing: **retrospective**

Last update: **2025-06-02, 1404/03/12**

Update count: **0**

Registration date

2025-06-02, 1404/03/12

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

Email address

komalbukhari608@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-14, 1403/10/25

Expected recruitment end date

2025-04-14, 1404/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Diclofenac Potassium Gel with and without Transcutaneous Electrical Nerve Stimulation in Primary Dysmenorrhea

Public title

Diclofenac Potassium Gel with and without Transcutaneous Electrical Nerve Stimulation in Primary Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

(18-45 years) primary or secondary dysmenorrhea Regular menstrual cycles (21-35days) Moderate to severe menstrual pain Participants were females experiencing PD not using hormonal contraception.

Exclusion criteria:

Pregnancy Females with bleeding disorders Breast feeding Uterine fibroids. Adenomyosis Endometriosis Pelvic inflammatory disease Menstrual disorder Hormonal contraceptive use Surgery or Procedures

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **376**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using the lottery method will be applied at the individual level without stratification. Participants will draw sealed slips to determine group allocation. Identical numbered white boxes will conceal treatment, and codes will be held by the principal investigator to maintain allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Statistical analyser and outcome assessor will be kept blind so that the result obtained will be without biasness.

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

2024-12-14, 1403/09/24

Ethics committee reference number

MIMAS/18/02/Komal

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.6

ICD-10 code description

Dysmenorrhea, unspecified

Primary outcomes

1

Description

pain

Timepoint

The primary outcome will be measured before the intervention and at 2 and 4 weeks after the intervention.

Method of measurement

WALIDD Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transcutaneous electrical nerve stimulation (TENS) therapy will be administered alongside diclofenac potassium gel. Transcutaneous electrical nerve stimulation (TENS) will be applied using a high-frequency setting of 80-100 hertz (Hz), a pulse duration of approximately 100 microseconds, and the intensity will be adjusted to produce a strong but comfortable tingling sensation without causing muscle contraction. Each session of transcutaneous electrical nerve stimulation (TENS) will last for 20 to 30 minutes and will be conducted two to three times per day during the 2 to 3-day treatment period

Category

Rehabilitation

2

Description

Control group: will be treated with 6% Diclofenac Potassium gel alone, the gel will apply to the lower abdomen and/or lower back at a dose of 2 to 4 grams per application, two to four times daily, beginning at the onset of menstrual pain and continuing for up to three days

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences

Full name of responsible person

Maliha Khalid Khan

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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

Muhammad Adnan Taj

Grant code / Reference number

MIMAS/18/2/Adnan

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

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Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**Muhammad Institute of Medical and Allied Sciences,
Multan**Full name of responsible person**

Muhammad Adnan Taj

Position

Student

Latest degree

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Other areas of specialty/work

Physiotherapy

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Postal code**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