

# 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

##### Phone

+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

##### Street address

Bosan Road

##### City

multan

##### Postal code

66000

##### Phone

+92 314 6361728

##### Email

malihatareen1997@gmail.com

### Sponsors / Funding sources

1

#### Sponsor

##### Name of organization / entity

Muhammad Institute of Rehabilitation Sciences, Multan

##### Full name of responsible person

qurat ul ain

##### Street address

Bosan Road

##### City

multan

##### Postal code

66000

##### Phone

+92 312 6754836

##### Email

qain0635@gmail.com

##### 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

Medical doctor

##### Other areas of specialty/work

Physiotherapy

##### Street address

Bosan Road

##### City

multan

##### Province

punjab

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##### Email

malihatareen1997@gmail.com

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Muhammad Institute of Medical Sciences and Rehabilitation

##### Full name of responsible person

Komal Ammar Bukhari

##### Position

lecturer

##### Latest degree

Medical doctor

##### 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**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

bosan road

**City**

multan

**Province**

punjab

**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