Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Instituite 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 Instituite 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 Instituite 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

Postal code
660000

Phone
+92 312 6862130

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

Street address
Bosan Road

City
multan

Province
punjab

Postal code
66000
Phone
+92 314 6361728
Email
komalbukhari608@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Muhammad Instituite 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
66000
Phone
+92 319 6826592
Email
muhammaddani0758@gmail.com

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