

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effects of abdominal strengthening exercises with and without transcutaneous electrical nerve stimulation in patient with primary dysmenorrhea.

Protocol summary

Study aim

To find the effects of Abdominal Strengthening exercises with and without Transcutaneous electrical nerve stimulation in patients with Primary Dysmenorrhea.

Design

Two groups, Single blinded, Randomized Controlled Trial.

Settings and conduct

The Perfect Physio And Spine Care Centre, Asjad Clinic, Minhaj Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Females aged 20 to 30 years; The characteristic of pain must be periodic (at least following 3 menstrual cycles) and gradually diminishes over 12 to 72 hours, ends after period. The pain must start generally in 2 to 3 years after start of menarche; regular menses (25-31 day). Exclusion Criteria: Chronic abdominal pain. Fibroids. Irritable bowel syndrome.

Intervention groups

Group A: Abdominal strengthening exercises with TENS.
Group B: Abdominal strengthening exercises without TENS.

Main outcome variables

Work, ability, Location, Intensity, Days of Pain, Dysmenorrhea (WaLIDD) Oswestry Disability Index (ODI) Numeric Pain Rating Scale (NPRS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045777N1**

Registration date: **2020-01-12, 1398/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-12, 1398/10/22**

Update count: **0**

Registration date

2020-01-12, 1398/10/22

Registrant information

Name

sana qaisar

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 42 35126110

Email address

maazqaisar00786@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-01-15, 1398/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of abdominal strengthening exercises with and without transcutaneous electrical nerve stimulation in patient with primary dysmenorrhea.

Public title

Effects of abdominal strengthening exercises with and without transcutaneous electrical nerve stimulation in patient with primary dysmenorrhea.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Females aged of 20 to 30 years. Nulliparous patients with symptoms of severe primary dysmenorrhea. The characteristic of pain must be periodic (at least following 3 menstrual cycles). Lower abdominal cramps or pelvic colic like pain that starts up to one day before menses lasts for the 3 days of bleeding. Gradually diminishes over 12 to 72 hours, ends after period. The pain must start generally in 2 to 3 years after menarche with regular menses (25-31 day).

Exclusion criteria:

Patients with history of pelvic inflammatory diseases (endometriosis, ovarian cysts). Chronic abdominal pain. Fibroids. Irritable bowel syndrome. Major abdominal or pelvic surgery. Intrauterine device and patients treated with oral contraceptive pills was contraindicated. Patients enrolled simultaneously into other studies that require drug intake or otherwise prevent compliance with protocol.

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Written informed consent will be taken. After enrollment into study, patient will be allocated either to group A or Group B by lottery method. No. of Chits will be equal to total sample size, odd Numbers will be allocated to Group A and even number will be allocated to Group B. Each patient will be requested to draw a hit from the box and after that patient will be recruited into either Group A or Group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor blind: Data Being secretive will be ensured by assigning specific identity number and all documents and forms will be placed in locker to blind assessors.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Secretary ethical review committee, Riphah College of Rehabilitation and Allied Health Sciences

Street address

28-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore

City

Lahore

Postal code

54000

Approval date

2019-09-19, 1398/06/28

Ethics committee reference number

Ref. No, RCR & AHS/REC/MS-NMPT/S19/007

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Pain

Timepoint

Before treatment and after completing the session

Method of measurement

Numeric pain rating scale (NPRS).

Secondary outcomes

1

Description

Low back pain/symptoms severity

Timepoint

Before and after completing treatment session

Method of measurement

Owestry disability index (ODI).

2

Description

Severity of dysmmenorrhea

Timepoint

Before and after completing the session

Method of measurement

Working ability, Location, Intensity, Days of pain, Dysmmenorrhea (WaLIDD).

Intervention groups

1

Description

Intervention group A Abdominal strengthening exercises with TENS

Category

Treatment - Other

2

Description

Intervention group B Abdominal strengthening exercises without TENS

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The Perfect Physio And Spine Care Centre

Full name of responsible person

Dr Saqib Fareed

Street address

The Perfect Physiotherapy and spine care Center,
Opposite Faisal Stadium, D.G. Khan Road, Muzaffar
Garh

City

Muzaffargarh

Postal code

34200

Phone

+92 66 2423000

Email

jugnomsf26@gmail.com

2

Recruitment center

Name of recruitment center

Minhaj hospital

Full name of responsible person

Dr Aslam Minhaj

Street address

Ganishwa pool, near puranl Sabiz Mandi, Minhaj
hospital.

City

Muzaffargarh

Postal code

34200

Phone

+92 66 2423000

Email

marifkhore@gmail.com

3

Recruitment center

Name of recruitment center

Asjad clinic

Full name of responsible person

Dr salma Ghouri

Street address

near city public school, karbala road, muzaffargarh

City

Muzaffargarh

Postal code

34200

Phone

+92 66 2423000

Email

kousarmehwish00786@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Muhammad Salman Bashir

Street address

28-M Quaid-e-Azam Industrial Estate, Kot Lakhpat,
Lahore

City

Lahore

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54000

Phone

+92 42 35126110

Email

chistisalman@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Riphah International University

Proportion provided by this source

20

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

Riphah International University

Full name of responsible person

Muhammad Salman Bashir

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

28-M, Quaid-e-Azam, Industrial Estate, Kot Lakhpat,
Lahore

City

Lahore

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+92 42 35126110

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

Riphah International University

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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