

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of Transcutaneous Electrical Nerve Stimulation along with Home Based Care Program in Postpartum Patients with Low Back Pain for Improving Pain, Disability and Quality of Life

Protocol summary

Study aim

The aim of the study is to compare the effects of Conventional Physical Therapy with and without Transcutaneous Electrical Nerve Stimulation in postpartum low back patients for improving pain, disability, and quality of life.

Design

A concealed, single-blinded, randomized controlled clinical trial with a parallel-group design of 70 patients,

Settings and conduct

70 subjects will be studied in Mansoor Hospital Department of Physical Therapy. Participants and assessors will be blinded. During the first visit, the researcher will complete thorough case history and regional assessment. Patients will be assessed using the SF36 for physical activity, general health, emotional activity, general health activity, and physical functions, Modified Oswestry Disability Index score for the functional outcome, and Numeric Pain Rating Scale for pain. In group A the patient will receive TENS and conventional Physical Therapy along with home-based exercises for back flexibility and strengthening and Group B will receive Conventional physical therapy along with home-based exercises. Participants were reassessed on the outcome scales at end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Age range between 18 to 40 years • Female having a normal delivery • Female with six Week post-partum • Female having low back pain of delivery
Exclusion Criteria • Female with an anatomical anomaly • Female with the structural disorder of spinal alignment (Scoliosis, kyphosis, lordosis) • Female with Traumatic / Inflammatory / Infectious Conditions • Female having diagnosed stress / depression / Anxiety

Intervention groups

Group A: TENS plus Conventional Physical Therapy (Supervised) with Home based exercises. Group B:

Conventional Physical Therapy (Supervised) with Home-based exercises

Main outcome variables

Pain, Disability, Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210205050256N2**

Registration date: **2021-09-03, 1400/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-03, 1400/06/12**

Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

Tooba Asif

Name of organization / entity

TIMES Institute

Country

Pakistan

Phone

+92 21 36410331

Email address

tooba573@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2022-01-01, 1400/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Transcutaneous Electrical Nerve Stimulation along with Home Based Care Program in Postpartum Patients with Low Back Pain for Improving Pain, Disability and Quality of Life

Public title

Effects of Transcutaneous Electrical Nerve Stimulation with Home-Based Program in Postpartum Patients with Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range between 18 to 40 years Female who have normal delivery Female with six week post-partum Female having low back pain

Exclusion criteria:

Anatomical anomaly Structural disorder of spinal alignment (Scoliosis, kyphosis, lordosis) Traumatic / Inflammatory / Infectious Conditions Diagnosed stress / depression / Anxiety

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In each group, 70 patients will be randomly distributed to two groups with the use of the lottery method of randomization. Slips will be prepared from 1 to 70. They will be homogeneous in shape, color, and size etc. Furthermore, they will be shuffled and will be placed in a box. The selected 35 slips will be allocated to Group 1, who will receive TENS plus supervised conventional home physical therapy program and the other 35 will be allocated to Group 2, who will receive conventional home physical therapy program.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor blinding: Every patient will be assessed by an independent assessor at the start and end of total treatment sessions to keep the assessment unbiased.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board

Street address

1 km Defence Road, Bhubatian Chowk. Lahore

City

Lahore

Postal code

54000

Approval date

2020-03-04, 1398/12/14

Ethics committee reference number

IRB/UOL/FAHS/719-II/2020

Health conditions studied**1****Description of health condition studied**

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low Back Pain

Primary outcomes**1****Description**

Pain

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Numeric Pain Rating Scale (NPRS)

2**Description**

Disability

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Modified Oswestry Disability Index (MODI)

3**Description**

Quality of Life

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Short-Form 36

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The patients in this group will receive TENS and conventional physical therapy along with home-based exercises. The electrodes of the TENS will be placed below shoulder blade level (T8), T10, L1, and sacral dimple level (S3). In conventional treatment, it will be hot pack and lumbar isometrics. Home-based exercises will include bridging, ankle pumps and straight leg raises with 1 set and 10 repetitions.

Category

Treatment - Devices

2

Description

Intervention group 2: The patients in this group will receive only conventional physical therapy along with home-based exercises. In conventional treatment, it will be a hot pack and lumbar isometrics. Home-based exercises will include bridging, ankle pumps and straight leg raises with 1 set and 10 repetitions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mansoor Hospital

Full name of responsible person

Dr. Farzana Shaukat

Street address

Multan Chungi, Lahore

City

Lahore

Postal code

54000

Phone

+92 42 35419510

Email

hirashafiq555@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Dr. Bilal Umar

Street address

1 km Defence Road, Bhubatian Chowk. Lahore

City

Lahore

Postal code

54000

Phone

+92 42 32300865

Email

info@uol.edu.pk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Lahore

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

Sponsor: country of origin

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of Lahore

Full name of responsible person

Dr. Bilal Umar

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

1 km Defence Road, Bhubatian Chowk. Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 42 32300865

Email

info@uol.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Lahore

Full name of responsible person

Dr. Bilal Umar

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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1 km Defence Road, Bhobatian Chowk. Lahore

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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

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

University of Lahore

Full name of responsible person

Hira Shafiq

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy