

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 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

**Street address**

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