Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Mansoora 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

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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, Bhobatian 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

Mansoora 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, Bhobatian Chowk. Lahore

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Master
Other areas of specialty/work
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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
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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