

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

COMPARATIVE EFFECTS OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AND LABOR EXERCISES ON PAIN, DURATION AND BEHAVIORAL RESPONSE OF PRIMIGRAVIDA WOMEN

Protocol summary

Study aim

To find the comparative effects of Transcutaneous Electrical nerve stimulation and labor exercises on pain, duration and behavioral response of primigravida women.

Design

Study design was randomized control trial

Settings and conduct

Study Setting was Gynecological Department, Social Security Hospital, Multan Road, Lahore.

Participants/Inclusion and exclusion criteria

Inclusion criteria encompassed females aged 20-35, primigravida women at 38 to 40 weeks' gestation, experiencing the first stage of labor with cervical dilation between 3 to 4 centimeters. Exclusion criteria included females with uterine issues, cervical cerclage, hypertension, urinary incontinence, or diagnosed psychological issues.

Intervention groups

Both groups received transcutaneous electrical nerve stimulation as conventional therapy. Group A received TENS along with labor exercises, while Group B received TENS without labor exercises.

Main outcome variables

Pain, Duration and behavioral response

General information

Reason for update

Acronym

TENS (Transcutaneous Electrical Nerve Stimulation)

IRCT registration information

IRCT registration number: **IRCT20240730062587N1**

Registration date: **2024-09-07, 1403/06/17**

Registration timing: **retrospective**

Last update: **2024-09-07, 1403/06/17**

Update count: **0**

Registration date

2024-09-07, 1403/06/17

Registrant information

Name

Sara Khan

Name of organization / entity

University Of Lahore,Lahore,Pakistan

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-01, 1402/07/09

Expected recruitment end date

2024-05-15, 1403/02/26

Actual recruitment start date

2023-10-10, 1402/07/18

Actual recruitment end date

2024-05-31, 1403/03/11

Trial completion date

2024-06-01, 1403/03/12

Scientific title

COMPARATIVE EFFECTS OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AND LABOR EXERCISES ON PAIN, DURATION AND BEHAVIORAL RESPONSE OF PRIMIGRAVIDA WOMEN

Public title

comparison of TENS with and without labor exercises during labor.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Females 20-35 years Primigravida women with 38 weeks to 40 weeks' gestation First stage of labor Cervical dilatation 3 cms to 4 cms as per vaginal findings Physically Active

Exclusion criteria:

Female with any other uterine issue Cervical cerclage Hypertension Urinary Incontinence Diagnosed Psychological issues.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

All the screened and willing participants was randomly allocated to two groups by lottery method.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was a single blinded study in which the assessor was kept blinded.

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

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

Research Ethics Committee

Street address

University of Lahore near bhuptian chowk,1km defense road, Lahore

City

Lahore

Postal code

54000

Approval date

2023-09-27, 1402/07/05

Ethics committee reference number

REC-UOL-565-10-2023

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

Labor is one of the most thrilling times in a women's life. Pregnant women typically have intense pain during this time. Both pharmaceutical and non-pharmacological methods exist for treating pain, and a variety of factors, such as psychological aspects or traumatic experiences in the past, can alter how pain is perceived.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

5 times after intervention with 45 mins interval

Method of measurement

Wong baker faces pain scale

2**Description**

Behavioral Response

Timepoint

5 times after intervention with 45 mins interval

Method of measurement

behavioral pain scale

Secondary outcomes

empty

Intervention groups**1****Description**

Experimental group A: Transcutaneous Electrical Nerve Stimulation (TENS) with Labor exercises. The study included two distinct groups: experimental and control. Participants in the experimental group had both Transcutaneous Electrical Nerve Stimulation (TENS) therapy and particular labor exercises. They were briefed on the functionality and benefits of TENS and given demonstrations. TENS electrodes were placed at the T10-L1 area. TENS was applied for 5 mins with continuous mode (frequency 150 Hz) and 5 sets of labor exercises having 5 repetitions each with interval of 45 minutes. In addition, the experimental group did labor exercises such as deep breathing, squatting, using birth balls, pelvic rocking, and lunges, Throughout the early labor period, the investigator encouraged and supported the primigravida women in the experimental group.

Category

Rehabilitation

2**Description**

Control Group B: Transcutaneous Electrical Nerve Stimulation (TENS) without Labor exercises. The study included two participant groups: experimental and control. The control group only got Transcutaneous Electrical Nerve Stimulation. Participants in this group were given a demonstration of TENS's benefits and functionality. TENS electrodes were then placed in the T10-L1 area, TENS was applied for 5 mins with continuous mode (frequency 150 Hz) and 5 sets of labor exercises having 5 repetitions each with interval of 45 minutes.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Punjab employees social security hospital (PESSI),
Multan Road, Lahore

Full name of responsible person

Dr. Fariha Khalid

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

not applicable

Grant code / Reference number

no

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

Yes

Title of funding source

University Of Lahore

Proportion provided by this source

100

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**

University Of Lahore

Full name of responsible person

Sara Khan

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street addressUniversity Of lahore, 1-km defense road, near
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Assistant Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

availale

To whom data/document is available

academic institutions

Under which criteria data/document could be used

SPSS

From where data/document is obtainable

Sara Khan sara.kha3035@gmail.com 03004381040

What processes are involved for a request to access data/document

postal address

Comments

no