Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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PESSI, Multan Road, Lahore

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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

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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Position
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Master

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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