

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Transcutaneous Electrical Nerve Stimulation on labor pain among nulliparous women

Protocol summary

Summary

The aim of this study is to determine the effect of percutaneous electrical nerve stimulation on labor pain. This study is a clinical trial with random allocation that samples will be divided in three group: intervention, placebo and control . Inclusion criteria will be: Nulliparous women; singleton; cephalic; gestational age 38-42 week; active phase; intact membranes. Exclusion criteria : Intra Uterine growth Restriction; cesarean indication ; medical and obstetric disease; experience of using Transcutaneous Electrical Nerve Stimulation ; skin irritation in place of electrodes; chronic disease; fetal distress. In 4 dilatation before insert Transcutaneous Electrical Nerve Stimulation device pain severity will be assessed by pain numerical scale. Then Transcutaneous Electrical Nerve Stimulation electrode will be insert .After that patient's pain will be assessed every one hour till end of first stage of childbirth , second stage and 4 hours after childbirth. Duration of first and second stage of labor will be checked. In placebo group electrodes insert in the same place of intervention group but it will not be on. In control group there is not any intervention and patients received routine care . In placebo and control groups, stage duration and severity pain will be assessed as the intervention group.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016020914556N3**

Registration date: **2017-01-10, 1395/10/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-10, 1395/10/21

Registrant information

Name

Roonak Shahoei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 1120

Email address

roonak.shahoei@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Kurdistan University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2016-10-31, 1395/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transcutaneous Electrical Nerve Stimulation on labor pain among nulliparous women

Public title

Effect of Transcutaneous Electrical Nerve Stimulation on labor pain among nulliparous women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous women referred to birth

ward of Beasat hospital ; singleton;cephalic; gestational age 38-42 week; active phase;intact membranes
Exclusion criteria : Intra Uterine growth Restriction;cesarean indication ; medical and obstetric disease; experience of using Transcutaneous Electrical Nerve Stimulation ; skin irritation in place of electrodes; chronic disease; fetal distress.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Closed envelop will be used for randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Passdaran Street- Kurdistan university of Medical Sciences- Sanandaj - Kurdistan _ Iran

City

Sanandaj

Postal code

66166

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

muk.rec.1394

Health conditions studied

1

Description of health condition studied

labor pain

ICD-10 code

ICD-10 code description

-

Primary outcomes

1

Description

Labor pain severity

Timepoint

First and second stage of labor and four hour after birth

Method of measurement

Numerical pain scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In 4 dilatation of cervix before using TENS, the severity of pain will be assessed by numerical scale. Then transcutaneous electrical nerve stimulation electrodes will be insert between 10th thoracic to lumbar first from 5 cm in middle line. Also 2 electrodes will be insert among second to fourth sacrum vertebral with the same interval. After that TENS will be on and intensity increase till the mother express tingling in the site of electrodes and the flow will be fixed. Then every one hour till end of first stage , during second stage and four hours after labor mother pain with numerical scale will be assessed and recorded. Also duration of first and second stage of labor will be recorded.

Category

N/A

2

Description

Placebo: In this group electrodes will be inserted as same as places of intervention group but the device will be off.

Category

N/A

3

Description

Control group: In this group there is not any intervention , just routine care will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital of Sanandaj- Kurdistan University of Medical Sciences

Full name of responsible person

Roonak Shahoei

Street address

Pasdaran Street, Kurdistan University of Medical Sciences, Sanandaj

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Roonak Shahoei

Position

PhD/ Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

PhD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kurdistan University of Medical Sciences

Full name of responsible person

Dr Rezaei

Street address

Pasdaran Street, Kurdistan University of Medical Sciences

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Roonak Shahoei

Position

Associate professor/ PhD

Other areas of specialty/work

Street address

Pasdaran Street, Kurdistan University of Medical Sciences, Sanandaj

City

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66166

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty