

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2017-01-10, 1395/10/21

#### 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.

#### 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

#### 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

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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**Email**

rshaho@yahoo.com

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## 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**

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66166

## Person responsible for scientific inquiries

**Contact**

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PhD/ Associate Professor

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*