

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of Transcutaneous Electrical Nerve Stimulation in post-cesarean pain

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of percutaneous electrical nerve stimulation on post cesarean pain. This study is a clinical trial with random allocation that samples will be divided in three groups: intervention, placebo, and control. Inclusion criteria will be singleton pregnancy, elective cesarean with transverse incision, same anesthesia, same gynecologist, same narcotic dose, newborn with apgar more 7, , having pain in incision site, do not have medical complications, do not use drugs. Exclusion criteria will be having pace maker, skin irritation, sensitivity to electrodes, fever and hemorrhage during 24 hour after cesarean . for evaluation of pain severity visual analog scale will be used. In three groups pain will be determined before intervention . Then in intervention group transcutaneous electrical nerve stimulation electrode will be insert and will be used for 30 minutes. After that pain will be assessed every 6 hours for 24 hours after cesarean and TENS device will be on for 30 minutes. Each time before and after intervention pain severity, blood pressure, breath rate and pulse will be evaluated. In placebo group electrods will be insert at the same place but device will be off. There is not any intervention for control group and they receive routine care. In this two groups assessment will be the same as intervention group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017020314556N4**  
Registration date: **2017-02-10, 1395/11/22**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-02-10, 1395/11/22

##### 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

2017-02-28, 1395/12/10

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Transcutaneous Electrical Nerve Stimulation in post-cesarean pain

##### Public title

Effect of Transcutaneous Electrical Nerve Stimulation in post-cesarean pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy, elective cesarean with transverse incision, same anesthesia, same gynecologist, same narcotic dose, newborn with apgar more 7, , having pain in incision site, do not have medical complications, do not use drugs. Exclusion criteria: having pace maker, skin irritation, sensitivity to electrodes, fever and hemorrhage during 24 hour after cesarean .

#### **Age**

No age limit

#### **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**

Using closed envelop for randomization.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

##### **Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

##### **City**

Sanandaj

##### **Postal code**

66166

#### **Approval date**

2016-12-13, 1395/09/23

#### **Ethics committee reference number**

IR.MUK.REC.1395/249

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Pain after cesarean

#### **ICD-10 code**

000-099

#### **ICD-10 code description**

Pain

## **Primary outcomes**

### **1**

#### **Description**

Pain severity after cesarean

#### **Timepoint**

Every 6 hours during 24 hours after cesarean

#### **Method of measurement**

VAS

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

International group: after cesarean pain-severity will be assessed with VAS . Then transcutaneous electrical nerve stimulation electrodes will be insert 5 Cm below and top of incision and device will be on for 30 minutes after that pain will be assessed again and in continue every 6 hours for 24 hours after cesarean.

#### **Category**

N/A

### **2**

#### **Description**

Placebo: In this group electrodes will be insert at the same place as intervention group but device will be off the evaluation is as the same.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Control group: There is not any intervention , just routine care will be done but evaluation will be the same.

#### **Category**

Treatment - Drugs

## **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**

**City**

Sanandaj

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

Kurdistan University of Medical Sciences

**Full name of responsible person**

Dr Rezaei

**Street address**Kurdistan University of Medical Sciences Pasdaran  
Street,,Sanandaj**City**

Sanandaj

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**PhD/ Associate professor of midwifery department,  
Kurdistan University of Medical sciences**Other areas of specialty/work****Street address**Kurdistan University of Medical Sciences Pasdaran  
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**Person responsible for updating data****Contact****Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

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**Position**

PhD Associate Professor

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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*