

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Transcutaneous electrical nerve stimulat<sup>io</sup> (TENS) in post-episiotomy pain

#### Protocol summary

##### Study aim

Determine the effect of transcutaneous electrical nerve stimulation (TENS) on post episiotomy pain

##### Design

This study is a clinical trial with random allocation that in this study 80 nuliparous women were randomly divided into two control and intervention group.

##### Settings and conduct

This study is a single blind clinical trial that samples of their belonging to a control group or the intervention are unaware and pain evaluation by a research associate, that unaware of the belonging people to the intervention group or control, will be done. For evaluation of pain severity, the numerical rating scale will be used

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous low-risk pregnancy, singleton pregnancy, gestational age 42-38 weeks, spontaneous vaginal delivery with mediolateral episiotomy, presenting pain in the episiotomy area, no use of analgesics during data collection. Exclusion criteria: side effects of TENS (burns, wounds, skin allergy), Not having epilepsy and mental illness, Not having heart pacemaker and heart disease

##### Intervention groups

In both groups pain will be determined before intervention. Then in the intervention group transcutaneous nerve stimulation electrode will be insert and will be used for 60 minutes. After that pain will be assessed during four specific time: before applying TENS, 30 minutes, 60 minutes and 120 minutes after removing TENS, at rest and activity (sitting and walking), pain severity, TENS side effects and blood pressure, respiratory rate and pulse rate will be evaluated.

##### Main outcome variables

Pain; Vital sign; side effect of transcutaneous electrical nerve stimulation (TENS); Mother's satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171224038034N1**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **prospective**

Last update: **2018-05-12, 1397/02/22**

Update count: **1**

##### Registration date

2018-02-17, 1396/11/28

##### Registrant information

##### Name

Soma Zakaryae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3316 1616

##### Email address

zakaryaei.s@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-20, 1397/01/31

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Transcutaneous electrical nerve stimulation (TENS) in post-epiotomy pain

**Public title**

Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in post-epiotomy pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Nulliparous low-risk pregnancy Singleton pregnancy Gestational age 42-38 weeks spontaneous vaginal delivery ( without use of vacuum and forceps) with mediolateral episiotomy presenting pain in the episiotomy area (pain score 4 or more) no use of analgesics during data collection

**Exclusion criteria:**

side effects of TENS (burns, wounds, skin allergy) Not having epilepsy and mental illness Not having heart pacemaker and heart disease

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using Blocked Randomization for randomization

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Samples of their belonging to a control group or the intervention are unaware and pain evaluation by a research associate, that unaware of the Belonging to the intervention group or control people will be done

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethic committee of Kurdistan University of Medical Sciences

**Street address**

Kurdistan University of Medical Sciences , Pasdaran

Street, Sanandaj

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

66166

**Approval date**

2018-02-04, 1396/11/15

**Ethics committee reference number**

IR.MUK.REC.1396/318

2

**Ethics committee**

**Name of ethics committee**

Ethic committee of Kurdistan University of Medical Sciences

**Street address**

Kurdistan University of Medical Sciences , Pasdaran Street, Sanandaj

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Sanandaj

**Province**

Kurdistan

**Postal code**

66166

**Approval date**

2018-02-18, 1396/11/29

**Ethics committee reference number**

IR.MUK.REC.1396/365

**Health conditions studied**

1

**Description of health condition studied**

Pain after episiotomy

**ICD-10 code**

G89.18

**ICD-10 code description**

Other acute postprocedural pain

**Primary outcomes**

1

**Description**

Pain severity after episiotomy

**Timepoint**

evaluating pain severity in before applying TENS, 30 minutes, 60 minutes and 120 minutes after removing TENS, at rest and activity (sitting and walking)

**Method of measurement**

NRS

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: The transcutaneous electrical nerve stimulation electrodes, 6-24 hours after episiotomy, will be inserted in parallel, near the episiotomy, in the region of the pudendal and genitofemoral nerve and device will be on for 60 minutes, after that pain will be assessed again during four specific times: before applying TENS, 30 minutes, 60 minutes and 120 minutes after removing TENS, at rest and activity (sitting and walking).

#### Category

N/A

### 2

#### Description

Control group: In this group electrodes will be inserted at the same place as the intervention group but the device will be off and the evaluation is 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

Seyedeh Soma Zakaryae

##### Street address

Kurdistan University of Medical Sciences, Sanandaj

##### City

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##### Province

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##### Postal code

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##### Phone

+98 87 3366 1120

##### Fax

+98 87 3366 0092

##### Email

ss.zakaryae@gmail.com

##### Web page address

<http://www.muk.ac.ir/Muk.aspx>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Dr Rezaei

##### Street address

Kurdistan University of Medical Sciences Pasdaran street, Sanandaj

##### City

Sanandaj

##### Province

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##### Email

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##### Web page address

<http://www.muk.ac.ir/Muk.aspx>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sanandaj University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### 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

Sanandaj University of Medical Sciences

##### Full name of responsible person

Seyedeh Soma Zakaryae

##### Position

Student Masters

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

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Kurdistan University of Medical Sciences, Pasdaran street, Sanandaj

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Seyedeh Soma Zakaryae

**Position**

student Masters

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Seyedeh Soma Zakaryae

**Position**

student Masters

**Latest degree**

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**Other areas of specialty/work**

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**Email**

ss.zakaryae@gmail.com

## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available