Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Transcutaneous electrical nerve stimulatio (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 Zakaryaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3316 1616

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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 stimulatio (TENS) in post-episiotomy pain

Public title
Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in post-episiotomy 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
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Street address
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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 insert 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 time: 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 insert at the same place as intervention group but device will be off and the evaluation is as 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 Zakaryaee

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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

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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 Zakaryaee

Position
Student Masters

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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