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

Kurdistan University of Medical Sciences,Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medicak 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 Medicak 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 Street,,Sanandaj

City

Sanandaj

Postal code

66166

Phone

+98 87 3366 1120

Fax

+98 733660092

Email

rshaho@yahoo.com

Web page address

muk.ac.ir

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

Street address

Kurdistan University of Medical Sciences Pasdaran Street,,Sanandaj

City

Sanandaj

Postal code

66166

Phone

+98 87 3366 1120

Fax

+98 87 3366 0092

Email

rshaho@yahoo.com

Web page address

muk.ac.ir

Person responsible for updating data

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

Street address

Kurdistan University of Medical Sciences Pasdaran Street,,Sanandaj

City

Sanandaj

Postal code

66166

Phone

+98 87 3366 1120

Fax

+98 87 3366 0092

Email

rshaho@yahoo.com

Web page address

mkk.ac.ir

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