

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of Transcutaneous Electrical Nerve Stimulation (TENS) on post Cesarean Section pain severity in comparison with the control group

Protocol summary

Study aim

The effect of Transcutaneous Electrical Nerve Stimulation (TENS) on post-Cesarean Section pain severity in comparison with the control group

Design

Clinical Trial, with two parallel groups, triple-blind, randomized, with 60 patients. The order of the patients was questioned from an external source who identified the sequence by the block randomized method.

Settings and conduct

Taleghani Hospital, Tehran, triple-blind (Researcher, Analyzer, Patients)

Participants/Inclusion and exclusion criteria

including criteria: women with a gestational age of more than 37 weeks; singleton; cephalic presentation; body mass index below 30 who are candidates for cesarean section. exclusion criteria: cesarean section due to umbilical cord prolapse; cesarean section in full dilation; mother's lack of proficiency in Persian language; drug addiction; history of chronic pain; continuous use of painkillers; history of using TENS; Performing an operation other than cesarean, such as tubal ligation and myomectomy during the operation.

Intervention groups

Intervention group: pregnant women candidates for caesarean section, who receive diclofenac suppository and pethidine to reduce pain after active TENS. Control group: pregnant women who are candidates for caesarean section, who receive diclofenac suppository and pethidine to reduce the pain after passive TENS..

Main outcome variables

Pain during hospitalization, pain at 2, 4, 6, 12, 24, and 48 hours after cesarean section, the level of satisfaction with pain relief, the use of painkillers, the level of side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170515033989N3**

Registration date: **2023-04-02, 1402/01/13**

Registration timing: **prospective**

Last update: **2023-04-02, 1402/01/13**

Update count: **0**

Registration date

2023-04-02, 1402/01/13

Registrant information

Name

Minoos Yaghmaei

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2590

Email address

m.yaghmaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Transcutaneous Electrical Nerve Stimulation (TENS) on post Cesarean Section pain severity in

comparison with the control group	
Public title	The effect of Transcutaneous Electrical Nerve Stimulation (TENS) on post Cesarean Section pain severity
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: pregnancy with a live fetus Single pregnancy cephalic presentation more than 37 weeks of gestational age Body mass index below 30 kg / m2 Candidate for termination of pregnancy with cesarean section Exclusion criteria: cesarean section due to cord prolapse and cesarean section in full dilation Mother's inability to speak Persian drug abuse history of chronic pain history of Continuous use of painkillers history of using tense other procedures like myomectomy or tubal ligation during cesarean section
Age	No age limit
Gender	Female
Phase	N/A
Groups that have been masked	• Participant • Outcome assessor • Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Block randomization method is used for randomization. In this way, ten blocks of six are used. In each block, there are three people in the control group and three people in the case group. In order for the random allocation process to be done correctly, a person who is not participating in the study forms the blocks using the website https://www.Randomization.com , in other words, the central randomization method is used. Every time the researcher found a patient who met the conditions to enter the study. He contacts the person responsible for random allocation and asks whether the patient is in the control group or the control group, and this continues until the samples are completed.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, TENS device is connected to both case and control groups, however, it is active in the case group and inactive in the control group. The person who fills in the questionnaire and records the outcomes, the person who performs the analysis, are blind to the membership of participants.
Placebo	Used
Assignment	Parallel

Other design features	
Secondary Ids	empty
Ethics committees	<u>1</u> Ethics committee Name of ethics committee Ethics Committee of Shahid Beheshti University of Medical Sciences Street address Shahid Beheshti University of Medical Sciences, Arabi st., Daneshjoo Blv, Shahriari sq., Evin, Tehran, Iran City Tehran Province Tehran Postal code 1985717413 Approval date 2023-03-07, 1401/12/16 Ethics committee reference number IR.SBMU.MSP.REC.1401.704
Health conditions studied	<u>1</u> Description of health condition studied cesarean section ICD-10 code 082.9 ICD-10 code description Delivery by caesarean section, unspecified
Primary outcomes	<u>1</u> Description The dose of painkillers (diclofenac suppositories and pethidine injections) Timepoint in first 6 hours, second 6 hours, second 12 hours, second day after cesarean section Method of measurement Dosage consumed (mg)- First, it is checked from the medical record and then it is confirmed by asking the patient. <u>2</u> Description pain Timepoint 2, 4, 6, 12, 24, 48 hours after cesarean section Method of measurement Numeral Visual scale (NVS)

3

Description

patient satisfaction with the analgesia process

Timepoint

6,12, 24, 48 hours after cesarean section

Method of measurement

Based on the question from the patient - bad - normal - good - excellent

4

Description

side effects

Timepoint

At the time of patient discharge

Method of measurement

Question from the patient and examination and mention of the complication

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of coupled TENS and pethidine and diclofenac suppositories to reduce pain in cesarean section patients. The method of administering pethidine 50 mg intramuscularly after the patient enters the ward and the method of administering diclofenac 1 tablet at least every 8 hours on the first and second day if the patient needs it. In this group, four TENS pads (HM-1000, made in South Korea) are placed, two in the lower abdomen and two in the waist area. TENS is set with a frequency of 80 Hz, with an intensity of 0 to 80 (according to the patient's wish) and the frequency will be 100 Hz. TENS will remain connected for up to 24 hours.

Category

Treatment - Devices

2

Description

Control group: Control group: Use of unbound TENS (placebo) and pethidine and diclofenac suppository to reduce pain in People who have undergone cesarean section. The method of administering pethidine is 50 mg intramuscularly after the patient enters the ward and the method of administering diclofenac is 1 tablet at least every 8 hours on the first and second day if the patient needs it. In this group, four TENS pads (HM-1000, made in South Korea) are placed two in the lower abdomen and two in the waist area, but the connection wire between the pad and the device is not connected. TENS will remain connected for up to 24 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Minoo Yaghmaei

Street address

Taleghani Hospital, Erabi street, Daneshjoo Blv, Shahriari sq, Evin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology

Street address

Shahid Beheshti university of Medical Sciences,, Arabi st., Daneshjoo Blv, Shahriari sq., Evin, Tehran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Yaghmaei

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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Position

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Maintain participant informations

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is available on demand after being unidentifiable

When the data will become available and for how long

Up to six months from the publication of the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Mention a valid request from the applicant

From where data/document is obtainable

Minoo Yaghmaei m.yaghmaei@sbmu.ac.ir

What processes are involved for a request to access data/document

must be emailed

Comments