Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Minoo Yaghmaei

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 2243 2590

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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

1

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

1

Description of health condition studied
cesarean section
ICD-10 code
082.9
ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

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.

2

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 conected. 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
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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

Academic

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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Person responsible for updating data

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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 Yaghmei m.yaghmaei@sbmu.ac.ir

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

Comments