Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determining and Comparing the Effect of Transcutaneous Electrical Nerve Stimulation at various points on pain intensity and satisfaction in patients undergoing cesarean section

Protocol summary

Summary

As a single-center, randomized, double-blind study, this research aims to examine the effect of Transcutaneous Electrical Nerve Stimulation (TENS) on pain intensity and satisfaction in patients undergoing cesarean section. The population consists of 18-45-year-old women undergoing cesarean section with general anesthesia. The inclusion criteria employed in this paper are the risk of anesthesia ASA Class 1, no history of anticonvulsants, opiates or painkiller usage, lack of pacemaker, no wound in the locations where electrodes are applied, no local anesthesia at the incision site and no discharge in less than 24 hours. 296 subjects are divided into four groups including group I (positioning electrodes at ST36 and stimulating), group II (placement of electrodes at 3 to 4 cm around the incision), group III (positioning electrodes at ST36 without stimulation) and group IV (without placement of electrodes). The type of anesthesia drug is the same in 4 groups. Patients' pain is measured immediately after consciousness by VAS. TENS machine with a fixed frequency of 2.5 Hz is used. Electrical stimulation is performed in two stages, each of which takes 30 minutes at 2-3 hour intervals. Then, postoperative pain is measured at the end of stage 1, before and after stage 2 and at the end of the first 24 postoperative hours. Patient satisfaction and doses of painkilles are compared between 4 groups 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062222866N1**
Registration date: **2015-09-14, 1394/06/23**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-09-14, 1394/06/23

Registrant information

Name

Nasrin Fadaee Aghdam

Name of organization / entity

Shahroud University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences- Vice Chancellor for Research Affairs

Expected recruitment start date

2015-08-21, 1394/05/30

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining and Comparing the Effect of Transcutaneous Electrical Nerve Stimulation at various points on pain intensity and satisfaction in patients undergoing cesarean section

Public title
The effect of Transcutaneous Electrical Nerve Stimulation (TENS) at various points on pain intensity and satisfaction in patients undergoing cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria are: 18 to 45 year-old women; the risk of anesthesia ASA Class 1(patients without any experience of organic, biochemical, physiologic or psychiatric disorders); no history of anticonvulsants; opiates or painkillers usage; lack of pacemaker; no wound in the locations where electrodes are applied; no local anesthesia at the incision site; no previous use of TENS and no discharge in less than 24 hours.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **296**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahroud University of Medical Sciences. Vice Chancellor for Research Affairs
Street address
Hafte-Tir Square. Shahroud University of Medical Sciences Shahroud
City
Shahroud
Postal code
Approval date
2014-01-29, 1392/11/09
Ethics committee reference number
IR.SHMU.REC.1394.20

Health conditions studied

1

Description of health condition studied
Cesarean pain
ICD-10 code
O82.0
ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Pain intensity
Timepoint
Immediately after consciousness, at the end of stage 1(after stimulation) , before and after stage 2(2-3 h after the first stage) and after the first postoperative 24 hours
Method of measurement
Visual Analogue Scale (VAS) and scored from 0 to 10

Secondary outcomes

1

Description
Satisfaction
Timepoint
24 hours after caesarean section
Method of measurement
Visual Analogue Scale (VAS) and scored from 0 to 10

2

Description
Doses of painkillers
Timepoint
24 hours after surgery
Method of measurement
recording the type and frequency of the drugs used

Intervention groups

1

Description
group 1: placement of electrodes with stimulation at ST36 or Zusanli point (one finger width lateral from the anterior border of the tibia)
Category
Prevention

2

Description
group 2: placement of electrodes in 3 to 4 cm around the incision with electrical stimulation
Category
Prevention

3

Description
group 3: placement of electrodes at ST36 without electrical stimulation
Category
Prevention

4

Description
Group 4: without placement of electrodes
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemiyeh Hospital
Full name of responsible person
Nasrin Fadaee Aghdam
Street address
Hafte-Tir Square, shahroud University of Medical Sciences , School of Nursing and Midwifery
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shahruod

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hassan Emamian, PhD
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Hafte-Tir Square, Vice Chancellor for Research, Shahroud University of Medical Science
City
Shahroud
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud University of Medical 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

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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