

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 painkillers 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

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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

City

shahruod

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian, PhD

Street address

Hafte-Tir Square, Vice Chancellor for Research, Shahroud University of Medical Science

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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

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Nasrin Fadaee Aghdam

Position

Faculty member

Other areas of specialty/work

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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