

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation and comparison Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in Lumbar & acupuncture points in reducing Labor Pain

Protocol summary

Study aim

Evaluation Effect of TENS in Lumbar & acupuncture on the reduction of Labor Pain

Design

In this study, 84 eligible pregnant women referring to maternity wards of Al-Zahra government Hospital in Rasht to be admitted for delivery in 2017, will be selected. Mothers are randomly assigned to four groups of A, B, C, D with a randomized balance block method of 1: 1: 1: 1 ratio.

Settings and conduct

This clinical trial study will be carried out to reduce the pain of normal labor during the delivery period at the Al-Zahra State Hospital in Rasht. Random sequences will be generated using the Random Generator program and will be assigned to the serial number in closed envelopes in the acceptance section and will be awarded to eligible individuals who are enrolled in the study, respectively. The code is recorded in the Patient Information Collection Form. The first operator (experienced medical staff experienced in labor and trained to use TENS at the relevant points) uses TENS on the bedside of mothers. The patient and the pain outcome evaluator (second operator) are not aware of the nature of the codes (double blind study).

Participants/Inclusion and exclusion criteria

Pregnant women aged 35-18 years old, Pregnancy age 41-37 weeks, single fetus with Cephalic presentation: Without the use of epidural analgesia or narcotics 12-24 hours before entering the study, without the experience of using TENS or acupuncture, absence of skin diseases in the area of intervention, absence of high risk pregnancy

Intervention groups

Four intervention groups are: A) Placebo control (Inactive lumbar and acupuncture TENS group). B) Active acupuncture TENS group. C) Active lumbar TENS group.

D) Active lumbar and acupuncture TENS group

Main outcome variables

Pain severity score: TENS satisfaction score: latent phase duration: active phase duration: first minute apgar: neonate fifth minute apgar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080826001096N6**

Registration date: **2018-05-02, 1397/02/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-02, 1397/02/12**

Update count: **0**

Registration date

2018-05-02, 1397/02/12

Registrant information

Name

Seyede Hajar Sharami

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in Lumbar & acupuncture points in reducing Labor Pain

Public title
Effect of TENS on the reduction of labor pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Pregnant women aged 35-18 years old Having reading and writing skills The gestational age: 41-37 weeks Single pregnancy Cephalic fetal presentation Latent phase of labor (dilatation less than 4-3 cm)
Exclusion criteria:
 Use of epidural analgesia or other anesthetics within 24 hours before entering the study The experience of using TENS or Acupuncture The use of oxytocin to induce and augmentation of labor before entering the study Mental and anatomical disorders (psychosis, schizophrenia, uterine abnormalities and pelvic stenosis) chronic diseases (heart disease, hypertension, diabetes) Skin diseases e (any lesion, inflammation and eczema) in the area of intervention high risk pregnancies (gestational hypertension, polyhydramnios and oligohydramnios known by ultrasound) Reduce fetal movements before entering the study Intrauterine growth retardation (IUGR) Rupture of membrane for more than 12 hours Use narcotics 12 hours before entering the study Infertility history

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Mothers are randomly assigned to four groups of A, B, C, D with a randomized balance block method of 1: 1: 1: 1 ratio. Random sequences will be generated using the Random Generator program and will be assigned to the serial number in closed envelopes in the acceptance section, and will be given to eligible individuals who are enrolled in the study, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description
Labor practitioners (the first operator) who have been trained to interview and complete the form and application of TENS on the suitable points, will be conducted on the mothers bedside. The relevant code is recorded in the patient's information collection form. The operator completes the demographic characteristics and delivery process of each patient in the coded form according to the medical records. The patient and the outcome evaluator of pain (second operator) do not know the nature of the codes (double blind study).

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

- Ethics committee of Guilan University of Medical Sciences

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN

City

Rasht

Province

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Postal code

66949- 41446

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.GUMS.REC.1396.300

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O83.9

ICD-10 code description

Assisted single delivery, unspecified

Primary outcomes

1

Description

Pain severity score

Timepoint

1. The beginning of the study, 2. One hour after the close of TENS 3. The beginning of the active phase (dilation of 4-5 cm) 4. The end of the first phase (full dilatation)

Method of measurement

visual analogue scale (VAS)

Secondary outcomes

1

Description

TENS satisfaction score

Timepoint

4 hours after childbirth

Method of measurement

Researcher made 3 questions questionnaire

Intervention groups

1

Description

Placebo control (Inactive lumbar and acupuncture TENS group): Lumbar and acupuncture points electrodes will be connected to the study participants and will receive very little stimulation (at 5 mA) without changing the frequency in a few seconds, so that the mother reports a tingling sensation. This flow is not repeated until the end of the first stage of labor. The pain score according to the schedule is measured in four stages.

Category

Placebo

2

Description

Intervention group: B) Active acupuncture TENS group: Lumbar and acupuncture points electrode-pads will be connected to the study participants. The acupuncture points TENS machine is in the hands of the trained operator. Based on body weight of the participants, the output current is stabilized at 10 to 18 mA. For a person of higher weight, you need to provide more effective electrical stimulation, which elicits a tingling sensation. For each mother, for half an hour, pulse are sent to acupuncture points. Repeated applications of TENS will be sent upon mother's request (up to 4 phase). The lumbar TENS machine is placed in the hands of the mother. Lumbar electrode-pads will receive very little stimulation (at 5 mA) without changing the frequency in a few seconds, so that the mother reports a tingling sensation. This flow is not repeated until the end of the first stage of labor. The pain score according to the schedule will be measured in four stages.

Category

Treatment - Devices

3

Description

Intervention group: Active Lumbar TENS group: Lumbar

and acupuncture points electrode-pads will be connected to the study participants. The Lumbar TENS machine is in the hands of the mother. The mother is taught how to increase the degree of electrical pulse with the onset of pain, which is the most pain-relieving effect, with the slightest sensation of tingling (Burst waves). Each time the contractions of labor, Boost waves sent by the mother. In this way, the pulse of the lumbar electrodes is sent to the mother's self-diagnosis to reduce pain at the onset of contractions. Then, the mother takes an active role. The acupuncture points TENS machine is in the hands of the trained operator. The acupuncture points electrodes send very little stimulation (at 5 mA) without changing the frequency in a few seconds, so that the mother reports a tingling transient sensation. This electrical current is not repeated until the end of the first stage of labor. The pain score according to the schedule will be measured in four stages.

Category

Treatment - Devices

4

Description

Intervention group: Active lumbar and acupuncture TENS group: Lumbar and acupuncture points electrode-pads will be connected to the study participants. The Lumbar TENS machine is in the hands of the mother. The mother is taught how to increase the degree of electrical pulse with the onset of pain, which is the most pain-relieving effect, with the slightest sensation of tingling (Burst waves). Each time the contractions of labor, Boost waves sent by the mother. The acupuncture points TENS machine is in the hands of the trained operator. For each mother, for half an hour, pulse are sent to acupuncture points. Repeated applications of TENS will be sent upon mother's request (up to 4 phase). The pain score according to the schedule will be measured in four stages.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr.Seyyedeh Hajar Sharami

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Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Research vice-chancellorship, Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Fatemeh Farjad Bastani

Position

gynocologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

There is still planning to share and publish.

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the study results.

To whom data/document is available

All interested in study.

Under which criteria data/document could be used

Not yet planned for it.

From where data/document is obtainable

sharami@gums.ac.ir

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

Not yet planned for it.

Comments