Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in Acupuncture Points (Hegu and Sanyinhiao) on Duration, labor Pain Intensity and Need for Induction of the First Stage of Labor: A Clinical Trial

Protocol summary

Study aim

Determining and comparing the effect of percutaneous electrical nerve stimulation in Hugo and San Injiao districts on the duration and severity of pain and the need for induction

Design

.In this study, a portable two-channel TENS device with two pairs of electrodes (Max Tens 2000) will be used. Before the intervention (dilation 3-5 cm), the intensity of pain in the three groups will be measured and recorded. In first group, two electrodes will be placed on the Hugo points on both hands, and in second group, two other electrodes will be placed on the San-Injiao points in both feet. In two groups, the device will be set with continuous current, frequency of 100 Hz per minute and wavelength of 250 microseconds, and will be alternately turned on for 20 minutes and turned off for 20 minutes, and will continue until the end of the second stage of labor (dilation of 10 cm to the exit of the fetus).

Settings and conduct

This study will be conducted on women in labor to assess the effect of TENS in Mousavi hospital in Zanjan. participants will be blinded.

Participants/Inclusion and exclusion criteria

Age 35-18 years. BMI below 30 Height above 150 Absence of pelvic stenosis based on examination by a researcher and Ankal doctor Gestational age is 42-37 weeks. Be primiparous.

Intervention groups

Samples are randomly entered into three groups of 42, so that in order to randomize the selection of samples by simple randomized method in one of the intervention groups 1 Hugo point , intervention 2 San-Ingiao or placebo group Placed.

Main outcome variables

Reducing pain intensity, reducing labor duration, reducing the need for induction in the active phase of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220221054085N1**
Registration date: **2022-10-27, 1401/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-27, 1401/08/05**
Update count: **0**

Registration date

2022-10-27, 1401/08/05

Registrant information

Name

sanaz Fayazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8373

Email address

sanazfaiiazi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in Acupuncture Points (Hegu and Sanyinhiao) on Duration, labor Pain Intensity and Need for Induction of the First Stage of Labor: A Clinical Trial

Public title

Comparison of the Effect of Transcutaneous Electrical Nerve Stimulation (TENS) in Acupuncture Points (Hegu and Sanyinhiao) on Duration, labor Pain Intensity and Need for Induction of the First Stage of Labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age is 18-35 years BMI below 30 Height above 150 Gestational age is 42-37 weeks. Be primiparous cephalic presentation No CPD based on examination by researcher and on-call Obstetrics Less than 6 hours have passed since the rupture of the membranes Education level is at least fifth elementary. Iranian no induction during labor no epilepsy. any use of painkillers since 3 hours before labor starts Must not be a user of cardiac pacemakers not to be addict no skin problem or scar in the region of electrodes contractions have started spontaneously single fetus no experience of using TENS before dilatation 3-5 cm

Exclusion criteria:

no tendency to continue participating in the study using the oxytocin or prostaglandin be necessary using any drug during the labor childbirth by cesarean method allergy or burn in the region of TENS electrodes

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **124**

More than 1 sample in each individual

Number of samples in each individual: **40**

A nulliparous pregnant woman without experience of using tennis in the active phase of labor

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are randomly entered into three groups of 42, so that in order to randomize the selection of samples by simple lottery method in one of the intervention groups 1 (Hugo point electrical stimulation), intervention 2 (San Ingiao electrical stimulation) or placebo group Placed. After assessing the participants according to inclusion criteria and taking consent, we will exclude a ball from a bag. the red ball means first group, green ball means second group, and the white one means placebo group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, one-way blinding will be performed and participants will be unaware that the device is turned on or not.

Placebo

Not used

Assignment

Parallel

Other design features

Previous studies have focused on determining the effect of the TENS device on reducing labor pain, while in this study we have tried to consider its effect on labor duration and the need to induce labor.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Zanjan university of medical sciences

Street address

No12, Khaje nasir Street,

City

Maraghe

Province

East Azarbaijan

Postal code

5513736363

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.ZUMS.REC.1398.0100

Health conditions studied

1

Description of health condition studied

Pain intensity and duration of labour and the need for induction in the active phase of labor

ICD-10 code

075.8

ICD-10 code description

075.8 Other specified complications of labour and delivery

Primary outcomes

1

Description
Duration of the first stage of labor: Accurate recording of the start time of the active phase from dilatation of 4 cm to complete dilatation of the cervix (will be measured on a minute scale).
Timepoint
from dilatation of 4 cm to complete dilatation of the cervix
Method of measurement
TV

2

Description
Pain ruler is a visual tool for determining the severity of pain through self-reporting. Scores range from 0 to 10. A score of 3-0 indicates mild pain, 4-7 indicates moderate pain, and 8-10 indicates severe pain.
Timepoint
from dilatation of 4 cm to complete dilatation of the cervix
Method of measurement
macGil ruler

3

Description
According to the diagnosis of the treating physician and recording the order to start induction of labor in the patient's file
Timepoint
from dilatation of 4 cm to complete dilatation of the cervix
Method of measurement
Trans vaginal examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention groups 1 (Hugo point electrical stimulation): In this study, the portable two-channel Max Tens 2000 device, which works with a battery, will be used with two pairs of electrodes. At the beginning of the intervention, when the person is in cervical dilatation of 3-4 cm, two electrodes will be placed in the Hugo area (located in the membrane between the thumb and index finger between the junction of the first and second metacarpal bones) in both hands and with continuous current, the frequency 100 Hz per minute and a wavelength of 250 microseconds will be set and alternately on for 20 minutes and off for 20 minutes, and this will continue until the end of the second stage of labor (dilation of 10 cm to the exit of the fetus).
Category
Treatment - Devices

2

Description
Intervention 2 (San Injiao Electrical Stimulation): In this study, a portable two-channel Max Tens 2000 device that works with a battery and two pairs of electrodes will be used. At the beginning of the intervention, since the dilatation of the cervix is 3-4cm, two electrodes will be placed in the San Injiao area in both legs (at a distance of 4 fingers from the fingers of the same person above the inner ankle) and with continuous current, the frequency of 100 Hz It will be set to 250 microseconds per minute and the wavelength will be alternately on for 20 minutes and off for 20 minutes, and this will continue until the end of the second stage of labor (dilation of 10 cm to the exit of the fetus).
Category
Treatment - Devices

3

Description
Control group: Placebo: In this study, the portable two-channel Max Tens device that works with a battery and two pairs of electrodes will be used. In this group, from the time of 3-4 cm dilatation of the cervix, two electrodes will be installed on the Hugo points on the hands and two electrodes on the San Injiao points on both feet, but no electric current will be established and the client will not know about the absence of current. Because we will turn on the device. And after the completion of the second stage of labor, the electrodes will be removed.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Mousavi educational Hospital
Full name of responsible person
Sanaz Fayazi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
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
Zanjan University of Medical Sciences

Proportion provided by this source
30

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
Zanjan University of Medical Sciences
Full name of responsible person
Sanaz Fayazi
Position
Faculty member- instructor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Personal information will not be identifiable after encryption.

When the data will become available and for how long

tarting 6 months after publication

To whom data/document is available

There are no restrictions on data presentation.

Information can be provided after the publication of the article

Under which criteria data/document could be used

Data are presented for comparison and systematic studies

From where data/document is obtainable

To receive data, you can contact Sanaz Fayazi, az email address sanaz faiiazi@gmail.com 09128216204پ

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

After the publication of the article, the data will be submitted within 10 days if the applicants receive an email or a call.

Comments

No comment