Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Transcutaneous Electrical Nerve Stimulation on labor pain among nulliparous women

Protocol summary

Summary

The aim of this study is to determine the effect of percutaneous electrical nerve stimulation on labor pain. This study is a clinical trial with random allocation that samples will be divided in three group: intervention, placebo and control . Inclusion criteria will be: Nulliparous women; singleton; cephalic; gestational age 38-42 week; active phase; intact membranes. Exclusion criteria : Intra Uterine growth Restriction; cesarean indication ; medical and obstetric disease; experience of using Transcutaneous Electrical Nerve Stimulation ; skin irritation in place of electrodes; chronic disease; fetal distress. In 4 dilatation before insert Transcutaneous Electrical Nerve Stimulation device pain severity will be assessed by pain numerical scale. Then Transcutaneous Electrical Nerve Stimulation electrode will be insert .After that patient's pain will be assessed every one hour till end of first stage of childbirth , second stage and 4 hours after childbirth. Duration of first and second stage of labor will be checked. In placebo group electrodes insert in the same place of intervention group but it will not be on. In control group there is not any intervention and patients received routine care . In placebo and control groups, stage duration and severity pain will be assessed as the intervention group.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016020914556N3**
Registration date: **2017-01-10, 1395/10/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-10, 1395/10/21

Registrant information

Name
Roonak Shahoei
Name of organization / entity
Kurdistan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Kurdistan University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2016-10-31, 1395/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transcutaneous Electrical Nerve Stimulation on labor pain among nulliparous women

Public title

Effect of Transcutaneous Electrical Nerve Stimulation on labor pain among nulliparous women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous women referred to birth

ward of Beasat hospital ; singleton;cephalic; gestational age 38-42 week; active phase;intact membranes Exclusion criteria : Intra Uterine growth Restriction;cesarean indication ; medical and obstetric disease; experience of using Transcutaneous Electrical Nerve Stimulation ; skin irritation in place of electrodes; chronic disease; fetal distress.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Closed envelop will be used for randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Passdaran Street- Kurdistan university of Medical Sciences- Sanandaj - Kurdistan _ Iran

City
Sanandaj

Postal code
66166

Approval date
2016-03-02, 1394/12/12

Ethics committee reference number
muk.rec.1394

Health conditions studied

1

Description of health condition studied
labor pain

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
Labor pain severity

Timepoint
First and second stage of labor and four hour after birth

Method of measurement
Numerical pain scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In 4 dilatation of cervix before using TENS, the severity of pain will be assessed by numerical scale. Then transcutaneous electrical nerve stimulation electrodes will be insert between 10th thoracic to lumbar first from 5 cm in middle line. Also 2 electrodes will be insert among second to fourth sacrum vertebral with the same interval. After that TENS will be on and intensity increase till the mother express tingling in the site of electrodes and the flow will be fixed. Then every one hour till end of first stage , during second stage and four hours after labor mother pain with numerical scale will be assessed and recorded. Also duration of first and second stage of laber will be recorded.

Category
N/A

2

Description
Placebo: In this group electrodes will be inserted as same as places of intervention group but the device will be off.

Category
N/A

3

Description
Control group: In this group there is not any intervention , just routine care will be done.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital of Sanandaj- Kurdistan University of Medical Sciences

Full name of responsible person
Roonak Shahoei

Street address
Pasdaran Street, Kurdistan University of Medical Sciences, Sanandaj

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Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Kurdistan University of Medicak Sciences

Full name of responsible person
Dr Rezaei

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Pasdaran Street, Kurdistan University of Medical Sciences

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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
Vice chancellor for research,Kurdistan University of Medicak 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
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Position
Associate professor/ PhD

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