Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of electrical nerve stimulation with and without flow through the skin (TENS) with supportive psychological intervention on labor pain and its maternal and neonatal consequences in pregnant women

Protocol summary

Study aim

Comparison of electrical nerve stimulation with and without flow through the skin (TENS) with supportive psychological intervention on labor pain and its maternal and neonatal consequences in pregnant women referring to the delivery block

Design

The clinical trial has two intervention groups and a control group in the form of double-blindness. The lottery will be performed on 90 pregnant women, ie 30 people in each group.

Settings and conduct

In the tennis group, starting the active phase of labor (cervical dilatation ≥4), the MAXTENS 2000 tennis machine with two pairs of electrodes will be used in the counseling group since the active phase of labor. Expressing energetic and hopeful sentences, teaching breathing and relaxation techniques during and in between contractions, promoting female self-esteem during childbirth and performing mindfulness techniques are the main cases of psychological supportive intervention. In the control group, routine labor care is performed. The research site is the Holy Prophet Hospital in Kerman. The intervening person is the researcher. But the person who evaluates the pain and the outcome of labor and the baby and the person who analyzes the data are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the following: 1. Be the first delivery 2. Be of Iranian nationality 3. Be 40-18 years old 4. Have a gestational age of 41-37 weeks 5. Pregnancy is single 6. The appearance of the fetus is cephalic 7. The active phase of labor has begun (dilatation ≥4) Exclusion criteria: 1. Stable fetal heartbeat disorder 2. Excretion of concentrated meconium 3. The patient refuses to continue the study

Intervention groups

Tens group; supportive psychological intervention group

Main outcome variables

Rate of mother pain; delivery morbidity; neonatal Apgar in the first and fifth minute

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151103024866N15**
Registration date: **2021-06-04, 1400/03/14**
Registration timing: **prospective**

Last update: **2021-06-04, 1400/03/14**
Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

Katayoun Alidousti

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

alidoosti@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of electrical nerve stimulation with and without flow through the skin (TENS) with supportive psychological intervention on labor pain and its maternal and neonatal consequences in pregnant women

Public title
Comparison of electrical nerve stimulation with and without flow through the skin (TENS) with supportive psychological intervention on labor pain and its maternal and neonatal consequences in pregnant women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The first delivery Iranian nationality Age 40-18 Having gestational age of 41-37 weeks Single pregnancy Cephalic presentation The active phase of labor has begun (dilatation ≥4)
Exclusion criteria:
History of epidural analgesia Presence of a sore or scar or inflammation at the junction of the tens probe with with a pacemaker Has a chronic underlying disease used painkillers 3 hours before the intervention and during the intervention Addicted to cigarettes and drugs and alcohol Have a clear and recognizable barrier to normal delivery at the time of sampling Have a history of cesarean section Diagnosed, untreated mental illness
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The lottery method was used for randomization. In such a way that on three papers, one number 1, one number 2 and one number 3 were written. The papers were folded and each pregnant woman who was eligible to enter the study picked up one of these papers. Number 1 was the tennis group, number 2 was the counseling group, and number 3 was the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher divided the people into three groups by lottery and the intervention was performed by the researcher. But the assessor of the outcome was the midwife who performed the delivery and had no knowledge of the intervention or control, nor did the data analyzer know the individuals.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2020-07-12, 1399/04/22
Ethics committee reference number
IR.KMU.REC.1399.330

Health conditions studied

1

Description of health condition studied
pain level during childbirth
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain level during childbirth based on Visual Analogue Scale
Timepoint
At the beginning of the study (dilatation ≥4) and the end of the first stage of labor (dilatation 10 cm)
Method of measurement
Visual Analogue Scale for pain

Secondary outcomes

1

Description
Neonatal Apgar
Timepoint
first and fifth minutes
Method of measurement
Apgar table

2

Description
delivery morbidity
Timepoint
during childbirth till one hours postpartum
Method of measurement
observational and gynecologist opinion

Intervention groups

1

Description
Intervention group: Tens group: With the start of the active phase of labor (cervical dilatation ≥4), the MAXTENS 2000 tennis device with two pairs of electrodes will be used, so that the upper electrodes between the L1-T10 vertebrae and the lower electrodes between the S2-S4 vertebrae at a distance of 7 cm on both sides of the spine Are placed. The device is set with continuous current, frequency of 100 Hz per minute and wavelength of 250 microseconds and continues until the beginning of the second stage of labor (dilation 10 cm).
Category
Treatment - Other

2

Description
Intervention group: Supportive and psychological Counselling group: The trained midwife has been present in the counseling group since the active phase of labor. Expressing energetic and hopeful sentences, teaching breathing and relaxation techniques during and in between contractions, promoting female self-esteem during childbirth and performing mindfulness techniques are the main cases of psychological supportive intervention.
Category
Behavior

3

Description
Control group: The control group performs routine labor care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Payambar Azam Hospital of Kerman city
Full name of responsible person
Fereshteh Moradi
Street address
Abuhamed Street,Kerman<Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3226 0041
Email
kalidousti@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr.Pardakhti
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5000
Email
kalidousti@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
1
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
Kerman University of Medical Sciences

Full name of responsible person
Katayoun Alidousti

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5219

Email
kalidousti@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Katayoun Alidousti

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5219

Email
kalidousti@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Katayoun Alidousti

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5219

Email
kalidousti@gmail.com

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

Clinical Study Report
Yes - There is 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
The clinical report will be published as an article

When the data will become available and for how long
since the article be published

To whom data/document is available
All jobs can access the printed article

Under which criteria data/document could be used
If used for other research, they can use it as a reference to the published article

From where data/document is obtainable
Visit the site of the journal where the results will be published or email: kalidousti@gmail.com

What processes are involved for a request to access data/document
As soon as you see the e-mail and the purpose of requesting the results is clear, it will be sent up to 2 days later.

Comments