Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effects of trans-cutaneous electrical nerve stimulation (Interferential current (IFC))in comparison with sham IFC on labor pain among nulliparous women

Protocol summary

Study aim
The effects of Trans-cutaneous Electrical Stimulation(interferential current) on the labor pain in primiparous women

Design
A randomized controlled trail A double blinded , sample size =30 each group.

Settings and conduct
Four electrodes with dimensions of 8 x 6 cm with a distance of 5 cm from the mid line of the spine in the para-spinal T10-L1 and four in the S2-S4 vertebra are crossed. 30 to 45 min of electrical stimulation will be applied at the start of the active phase in the upper electrodes and 30 to 45 min at the end of the active phase in the lower electrodes. Control group: As a placebo group, the output will be zero.

Participants/Inclusion and exclusion criteria
Inclusion criteria: primiparous, one fetus, gestational age 37 to 42 weeks, early active phase, cephalic presentation of fetus. Exclusion criteria : heart disease, diabetes, high blood pressure, having pregnancy complications such as pre-eclampsia, gestational diabetes, hepatic syndrome, any skin problems in the electrodes location, unwillingness to use electrical stimulation

Intervention groups
Both groups will receive routine care. In the intervention group, 30 to 45 minutes of IF in the early active phase at T10-L1 levels and 30 to 45 minutes in the end of active phase will be applied at levels (S2-S4) with a base frequency of 4000 Hz , pulse frequency of 80 to 120 Hz and pulse duration of 50 to 60 microsecond. The control group will receive the sham IFC.

Main outcome variables
Pain: will be measured using the VAS scale Duration of the active phase of labor: will be determined by using a partograph chart

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140811018760N5**
Registration date: **2019-08-16, 1398/05/25**
Registration timing: **prospective**

Last update: **2019-08-16, 1398/05/25**
Update count: **0**

Registration date
2019-08-16, 1398/05/25

Registrant information

Name
Fariba Ghaderi
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effects of trans-cutaneous electrical nerve stimulation (Interferential current (IFC))in comparison with sham IFC on labor pain among nulliparous women

Public title
The effects of trans-cutaneous electrical stimulation on labor pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Primiparity one fetus Gestational age 37 -42 Early stage of active phase(dilation 4cm) Cephalic presentation of fetus

Exclusion criteria:
mother heart disease mother Diabetes mother High blood pressure Pre-eclampsia HELP syndrome Any skin problems in where electrodes will be located unwillingness to use electrical stimulation

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Pregnant women who are at the start of active phase of labor (4 cm dilatation), if appropriate, were randomly assigned random block sizes of 4 and 6 blocks with a 1: 1 ratio in The two groups will intervention and control. For the Allocation Concealment, the type of intervention received is written on a piece of paper and placed inside the opaque envelopes, the back of the file will be numbered. The envelopes will be opened according to the entry of the participants and the type of group will be specified.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in this study will be blind in which group they are ,also the investigator(data assessor) will be blind about the individuals in the intervention or control group. And the data analyzer will be blind about data is related to the control group, or the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Daneshgah Ave., Rehabilitation Faculty, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5167631444

Approval date
2019-07-01, 1398/04/10

Ethics committee reference number
IR.TBZMED.REC.1398.370

Health conditions studied

1

Description of health condition studied
labor

ICD-10 code
080

ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
pain severity

Timepoint
The pain will be evaluated in several stages in both groups; first, before interventions and care, immediately after intervention, then every hour until the second stage of delivery, and at the end one hour after the delivery

Method of measurement
It will be measured using the Visual Analog Scale (VAS)

2

Description
Duration of the active stage of labor

Timepoint
We will measure the time from the start of the active phase (reaching dilatation to 4 cm) to the end of the active phase (dilatation reaches 8 cm).

Method of measurement
The duration will be determined from partography

Secondary outcomes

1

Description
Frequency of satisfactory labor progress
Timepoint
during the active phase of labor will be determined.
Method of measurement
It will be determined by examining the amount of dilatation of the cervix by vaginal examination, the fetal head descending , and the characteristics of uterine contractions by using partography.

2

Description
The frequency of using sedative medications
Timepoint
From the start of interventions to an hour after the completion of labor
Method of measurement
The amount of its using dose will be recorded in the partography

3

Description
Frequency of need for oxytocin injection
Timepoint
From the beginning of the interventions to the end of labor
Method of measurement
The use or non-use of oxytocin will be recorded in the form of a partograghy and, if used, the number of drops per minute will be recorded in the partography

4

Description
1st and 5th minute Apgar Score
Timepoint
The first and fifth minutes after birth will be checked.
Method of measurement
The Apgar score is obtained using the Apgar score table.

Intervention groups

1

Description
Intervention group: In this group, 30 to 45 minutes of electrical stimulation were obtained using a multistimulator (X735 Novin medical engineering company) at the start of the active phase (reaching the cervical dilatation of 4 cm in high electrodes and 30 to 45 minutes late in the active phase(cervical dilatation of 8 to 10 cm) will be applied at lower electrodes with a base frequency of 4000 Hz , a beat frequency of 80 to 120 Hz and pulse duration of 50 to 60 microseconds, in addition to routine care.
Category
Other

2

Description
Control group: They will be treated as a placebo group and the electrodes are similar to the intervention group and will be operated in the same phase with the intervention group, only the output of the device will be zero. Both groups will receive routine care that includes checking vital signs of the mother and the fetus, the condition of the fetues, the status of the pouch, the need for oxytocin and medication.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Fariba Ghaderi
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South Artesh Ave., ALzahra Hospital, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Research Vice-Chancellor, Daneshgah Ave., Tabriz, Iran
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Fariba Ghaderi
Position
Associate professor
Latest degree
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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In case of IPD, participant data sets could be shared

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions in Iran

Under which criteria data/document could be used

In case of journal or reviewers request for data set

From where data/document is obtainable

Via email and giving documents to prove their identity

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

Sending email and documents to prove their identity

Comments