Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of Transcutaneous Electrical Nerve Stimulation (TENS), the aromatherapy of lavender and physiologic delivery without medication on the neonatal and maternal outcome

Protocol summary

Study aim
"Comparative study of Transcutaneous Electrical Nerve Stimulation (TENS) and the aromatherapy on vaginal delivery"

Design
Clinical trial with control group, with parallel groups, without blinding, randomized on 150 patients

Settings and conduct
In this study, we performed on 150 patients with a gestational age of more than 38 weeks. The patients are divided into three group including the aromatherapy of lavender (1 cc of 20% lavender solution is soaked in a cloth and attached to the mother's breast at the beginning of the active phase of labor), the method of transcutaneous electrical nerve stimulation (electrical stimulation with intensity of 10-18 mA and frequency of 100 Hz for 30 minutes with the start of the active phase of labor) and control. Labor pain, maternal and fetal outcomes, and duration of labor are compared in groups.

Participants/Inclusion and exclusion criteria
Single pregnancy with cephalic presentation and having a low-risk pregnancy and not taking illicit drugs and no previous history of anxiety and depression

Intervention groups
Intervention group 1: The patients are received aromatherapy of lavender in during the active phase of labor. Intervention group 2: The patients are received transcutaneous electrical nerve stimulation method in during the active phase of labor. Control group: The patients with physiological delivery without intervention.

Main outcome variables
Pain rate; Duration of active phase; Average duration of stage II; Patient satisfaction (using a Likert scale of five); Baby Apgar score; Percentage of cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210501051151N1**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date
2021-09-29, 1400/07/07

Registrant information

Name
Maede Ebrahimian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of Transcutaneous Electrical Nerve Stimulation (TENS), the aromatherapy of lavender and physiologic delivery without medication on the neonatal and maternal outcome

Public title
"Comparative study of Transcutaneous Electrical Nerve Stimulation (TENS) and the aromatherapy on vaginal delivery"

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Single pregnancy Cephalic Low risk pregnancy Normal placenta and fetus status Satisfied to participate in the study

Exclusion criteria:
Drug abuser , smoker in pregnancy Previous history of periods of depression and anxiety and stressful life events in the last 6 to 12 months Mothers refuse to continue the intervention

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Each of the patients is provided with a particular number by Random Allocation software allocated them to an intervention group. Each patient is provided with a particular number. Cases with numbers corresponded for 3*k are allocated to transcutaneous electrical nerve stimulation group, those with numbers corresponded for 3*k+1 are allocated to aromatherapy with lavender essential oil and those with numbers corresponded for 3*k+2 are allocated to the groups physiological delivery without medication.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Isfahan , Isfahan University of Medical Sciences , Obstetrics and Gynecology Department

City
Isfahan

Province
Isfehan

Postal code
8174634446

Approval date
2019-04-20, 1398/01/31

Ethics committee reference number
IR.MUI.MED.REC.1398.007

Health conditions studied

1

Description of health condition studied
Normal Vaginal Delivery

ICD-10 code
Z38.00

ICD-10 code description
Single liveborn infant, delivered vaginally

Primary outcomes

1

Description
Pain severity

Timepoint
In the active phase of labor and the first half hour after delivery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the transcutaneous electrical nerve stimulation group, two pairs of electrode are placed in the spinal nerve roots T10-L1 and S2-S4 in the active phase of labor (5 cm dilatation of the cervix) and electrical stimulation with a intensity of 10-18 mA and a frequency of 100 Hz are established for 30 minutes.

Category
Rehabilitation

2

Description
Intervention group: One cc of 20% aromatherapy with lavender essential oil is impregnated on a 10 × 10 cm square cloth and attached to the mother's breast at the beginning of the active phase.
Category
Rehabilitation

3

Description
Control group: Physiological delivery without medication, except for midwifery care, no method is used to reduce the pain of the active phase of labor.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Vice President for Research and Technology
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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
Esfahan University of Medical Sciences
Proportion provided by this source
50
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
Esfahan University of Medical Sciences
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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
The part of the study data is provided to researchers and data that identifies patients is not provided to other researchers.

When the data will become available and for how long
Six months after publishing the results.

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable
By sending an email to the following address that belongs to the executor of the project: ebrahimian93.maede@gmail.com

What processes are involved for a request to access data/document
After reviewing the researcher's request and providing the required documents will be available.

Comments