

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3233 9450

##### Email address

ebrahimian93.maede@gmail.com

##### 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

Isfahan

#### 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

**Full name of responsible person**

Maede Ebrahimian

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Vice President for Research and Technology

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Isfahan University of Medical Sciences, Isfahan, 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**

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

**Full name of responsible person**

Maede Ebrahimian

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

Minoo Movahedi

**Position**

Associate Professor

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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**

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**