

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174634446

Phone

+98 31 3792 8001

Email

ebrahimian93.maede@gmail.com

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

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174634446

Phone

+98 31 3792 8001

Email

ebrahimian93.maede@gmail.com

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

Street address

Isfahan university of Medical sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

0098313668004

Email

ebrahimian93.maede@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Minoov Movahedi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Obstetrics and Gynecology Department, Isfahan

University of Medical sciences ,Isfahan

ebrahimian93.maede@gmail.com

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

movahedi@med.mui.ac.ir

Person responsible for updating data

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

Street address

Obstetrics and Gynecology Department, Isfahan
University of Medical sciences ,Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

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