

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of Entonox gas compared with aromatherapy with Lavender on severity of nulliparous women's labor pain

#### Protocol summary

##### Study aim

Comparing the severity of pain before and after intervention among two groups patients who will receive Entonox gas and the aroma of lavender.

##### Design

A clinical trial with a sample size of 60 people randomly and double-blind and comparing the two intervention groups

##### Settings and conduct

Considering the importance of the issue of the promotion of normal delivery and the satisfaction of this process, a study will be conducted to determine the methods of diagnosis. A study will be conducted in the maternity ward of the Besat Hospital in Sanandaj. 60 people will be entered into the study after checking for entry and exit and obtaining written and informed consent. Individuals will be randomly assigned into two groups of intervention. The study will be blinded by a double-blind researcher and counselor. In the Entonox gaseous group, the mask will be absorbed in the pain according to the need of the mother, and in the aroma group, two drops of lavender essential oil will be placed at a distance of 7-10 cm from the mother's nose.

##### Participants/Inclusion and exclusion criteria

Entry criteria: Women aged 18 to 35 years old First pregnancy and term Healthy fetus Exclusion criteria: Mother's patients Embryonic problems Obstetric problems

##### Intervention groups

In this study, we will have two groups of interventions. Intervention in both groups will begin with 4 cm dilatation and the severity of pain will be measured with the Visual Analogue scale (VAS). In the Entonox gas group, the mask will be placed on the mouth and nose according to the needs of the mother, in the aromatherapy group, the researcher will drop two drops of lavender essential oil on sterilized gas and place it at a distance of 7-10 cm from the patient's nose, and the essential oil of the gas will be renewed every half an

hour.

##### Main outcome variables

Severity of labor pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170906036081N2**

Registration date: **2018-03-15, 1396/12/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-15, 1396/12/24**

Update count: **0**

##### Registration date

2018-03-15, 1396/12/24

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 015 0755

##### Email address

maedeh.sharghi@muk.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-01-21, 1396/11/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of Entonox gas compared with aromatherapy with Lavender on severity of nulliparous women's labor pain

**Public title**

Effect of Entonox gas compared with aromatherapy with Lavender on severity of labor pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 35 to 18 can enter the study. Women who are nulliparous can participate in the study. The position of the embryo should be cephalic. Amenotypic fluid volume of the mother is normal. The last trimester of ultrasound has reported the normal weight of the fetus. According to the first day of the last menstruation, the gestational age is greater than 38 weeks. The mother is healthy in terms of respiratory system and smell.

**Exclusion criteria:**

Hypertension in mother . Diabetes in mother. The mother has thyroid problems. The embryo is macrosomal. The fetus is a IUGR or low birth weight . Long-term rupture of the curtains for more than 18 hours. Polyhydramnios Oligohydramnios Embryonic anomalies have been diagnosed. Mothers have allergies and respiratory illness. An uncontrollable heartbeat of the fetus is created in the lab. SPO2 mother is less than 95% People who have contraindications to Entonox gas, such as head trauma, head stiffness, severe asthma, need for medical interventions in labor, are excluded from the study.

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

People will be randomly divided into intervention and control groups. The placement of individuals in the intervention group on the envelope is designed so that people will have equal odds.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

To prevent bias, the researcher will not measure the severity of pain after the intervention, and this will be done by a research collaborator. Information will be provided to the analyst without specifying intervention groups. Due to the LDR of the research room rooms, the

patient is unaware of the interventional groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

ethics committee of kurdistan university of medical sciences

**Street address**

Pasdaran street, Kurdistan University of Medical Science

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

661476 - 13446

**Approval date**

2018-02-05, 1396/11/16

**Ethics committee reference number**

IR.MUK.REC.1396.317

**Health conditions studied****1****Description of health condition studied**

Severity of labor pain

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Severity of labor pain

**Timepoint**

The severity of pain is measured in dilates 4-5, 6-7, 8-9, and 10 cm before and after the intervention.

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: In the group using Entonox gas, people will be trained to breathe the mask on their mouths, starting with a 4 cm dilatation. They should tell their severity before and after the use of Entonox gas based on the visual analogue scale ruler (VAS). The amount of pain will be recorded. Measuring the pain at dilates of 5-4 cm, 7-6 cm, 9-8 cm and 10 cm before and after using the entonox gas.

### Category

N/A

## 2

### Description

Intervention group : In a group of lavender fragrances, after 4 cm dilatation, the researcher will drop two drops of lavender essential oil prepared by Barich Essence on sterilized gas at a distance of 7-10 cm from the patient's nose. And every half an hour it will repeat the essential oil on the gas. The mother should tell her pain before and after the intervention based on the visual criteria of the VAS ruler in dilatations of 5-4 cm, 7-6 cm, 9-8 cm and 10 cm. This information will be recorded by the research fellow.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Department midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran

##### Street address

Keshavarz Ave, Beasat hospital

##### City

Sanandaj

##### Province

Kurdistan

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6617713391

##### Phone

+98 87 3328 5914

##### Fax

##### Email

info@muk.ac.ir

##### Web page address

<http://www.muk.ac.ir/Muk/Hospitals/Besat.aspx>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Kurdistan of Medical Science

##### Full name of responsible person

Farzin Rezai

##### Street address

Pasdaran Blvd, kurdistan university of medical science

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Sanandaj

##### Province

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6618634683

##### Phone

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##### Email

f.razaee@muk.ac.ir

##### Web page address

<http://www.muk.ac.ir>

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

The University of Kurdistan of Medical Science

##### 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

The University of Kurdistan of Medical Science

##### Full name of responsible person

Maedeh Sharghi Chalaki

##### Position

Master student of Kurdistan University of Medical Sciences

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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The University Kurdistan of Medical Science  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The demographic information of individuals without their identification will be recorded as an average in the final report and will be published along with the data from the study.

### When the data will become available and for how long

Starting the access period from 1397

### To whom data/document is available

Researchers working in academia and academia

### Under which criteria data/document could be used

Researchers working in academia and academia

### From where data/document is obtainable

maedeh.sharghi@muk.ac.ir

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

Send the email to the researcher.

### Comments