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 Entonax 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 Entonux 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 Entonux 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 wlli divide randomly divided into intervention and control groups. The placement of individuals in the interventions grope 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 Entonx 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

Postal code
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

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Phone
+98 87 3323 5445

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

Street address
Pasdaran Blvd, Kurdistan University of Medical Science

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Phone
+98 87 3323 5445

Email
maedeh.sharghi@muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Kurdistan of Medical Science
Full name of responsible person
Maedeh Sharghi Chalaki
Position
Midwifery student of Kurdistan University of Medical Sciences
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Pasdaran Blvd, Kurdistan University of Medical Science
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3323 5445
Email
maedeh.sharghi@muk.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
The University Kurdistan of Medical Science
Full name of responsible person
Maedeh Sharghi Chalaki
Position
Midwifery student of Kurdistan University of Medical Sciences
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Pasdaran Blvd, Kurdistan University of Medical Science
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3323 5445
Email
maedeh.sharghi@muk.ac.ir

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