# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparison of aromatherapy with lavender and Nitrous oxide on labor pain

## Protocol summary

**Study aim**
Comparison of the effect of aromatherapy with lavender and nitrous oxide on labor pain
**Design**
A clinical trial with a community-based control and control group, a blind, randomized, randomized clinical trial
**Settings and conduct**
Imam Khomeini Hospital of Shirvan Examples are blind to the study.
**Participants/Inclusion and exclusion criteria**
Age, gestational age, diploma literacy, single pregnancy, 4 cm dilatation, low risk pregnancy, informed consent and lack of: premature delivery, bleeding, pre-eclampsia, diabetes, seizure, history of acute and chronic pain, professional exercise, alcohol and cigarette addiction, receipt of pain medication, history of allergy to herbal, fetal distress, clear stenosis in the pelvic floor, known psychological disease and being in the active phase of labor
**Intervention groups**
In the aromatherapy group with lavender essential oil, mothers are required to smoke during cold shrinkage during shrinkage and pain. The use of nitrous oxide in the group begins with the onset of the active phase of labor.
**Main outcome variables**
Change in labor pain

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20180610040032N1**
Registration date: **2018-10-22, 1397/07/30**
Registration timing: **registered_while_recruiting**
Last update: **2018-10-22, 1397/07/30**
Update count: **0**
**Registration date**
2018-10-22, 1397/07/30

**Registrant information**
**Name**
Mohammad Zarei
**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**
2018-08-23, 1397/06/01
**Expected recruitment end date**
2018-12-21, 1397/09/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of aromatherapy with lavender and Nitrous oxide on labor pain

**Public title**
Comparison the effect of lavender and Nitrous oxide on labor pain
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Gestational age Between 37 and 42 weeks At least Diploma Literacy Singleton pregnancy 4 cm dilatation Low risk pregnancy (no rupture over 6 hours of water sac) Conscious consent of the individual to enter the study

**Exclusion criteria:**

Preterm delivery Third-trimester hemorrhage and intrauterine growth retardation Preeclampsia 24<BMI<18.5 History of acute and chronic pain such as migraine Performing professional exercise (due to changes in the threshold of pain and delivery phase) Drug Addiction, Alcohol and Smoking Receive analgesic within 3 hours before the onset of intervention History of allergy to herbal Diseases of internal and surgical diseases in mother and fetus Existence of fetal distress symptoms Clear stenosis in the pelvic floor Known mental disease Stay in active phase of labor Diabetes Seizure

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples are randomly assigned to two groups of aromatherapy with lavender and nitrous oxide gas.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this research, the subjects will not be aware of the type of intervention they will receive.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

**Street address**

Dolat Ave.

**City**

Bojnurd

**Province**

North Khorasan

**Postal code**

9414975516

**Approval date**

2018-07-24, 1397/05/02

**Ethics committee reference number**

IR.NKUMS.REC.1397.031

## Health conditions studied

### 1

**Description of health condition studied**

Pain

**ICD-10 code**

G89

**ICD-10 code description**

Pain, not elsewhere classified

## Primary outcomes

### 1

**Description**

Change in pain

**Timepoint**

Before the beginning of the study, at dilates 6-4, 8-6, 10-8 cm and immediately after intervention

**Method of measurement**

VAS

## Secondary outcomes

### 1

**Description**

Satisfaction Survey

**Timepoint**

End of research

**Method of measurement**

questionnaire

## Intervention groups

### 1

**Description**

Intervention group: In the lavender aromatherapy group, the essential oil produced by Barij Essen was used in the stoechas species, which is distilled with a concentration of 1.5% of the unopened flowers, and is given to mothers by means of masked cold-smoked incense. Mothers are asked to smoke during a contraction and pain through a cold-smoked mask.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In the Nitrosoxide group, training on the use of masks and how to breathe during use in women is given, and starting with the onset of active phase of labor, nitrous oxide gas begins. Mothers inhale the gas at the onset of the pain and stop the inhalation with the end of the pain and this procedure continues until the end of the second phase of labor.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Imam Khomeyni hospital
**Full name of responsible person**
Salimeh Azizi
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Imam Reza, Shirvan
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Seyed Kaveh Hojjat
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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**
Bojnourd University of Medical Sciences
**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**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Mohammad Zarei
**Position**
Educator
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
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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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
Give raw data after removing sample instances

**When the data will become available and for how long**
At the request of the publication of the article

**To whom data/document is available**
Reviewers journals, planners and authors interested in writing meta-analysis articles

**Under which criteria data/document could be used**
Observing the rights of researchers

**From where data/document is obtainable**
Submit a written request to corresponding author

**What processes are involved for a request to access data/document**
Submit a written request to corresponding author

**Comments**