

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The comparison of the effect of Entonox gas and Back massage on Labor pain in Pregnant Women

#### Protocol summary

##### Study aim

Comparison of the effect of Entonox gas and back massage on labor pain in pregnant women

##### Design

A clinical trial with one control group and two intervention groups of Entonox and back massage, with parallel groups, without blinding, randomized by block method, on 84 pregnant women. Random Allocation Software will be used for randomization.

##### Settings and conduct

Pregnant mothers who refer to Al-Hadi maternity hospital in Shushtar during the study will be included in the study if they are eligible and will be randomly assigned to 2 intervention groups and a control group. This study will be conducted without blinding.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: women with term pregnancy and less than 4 births, with regular spontaneous uterine contractions in the active phase of labor. Exclusion criteria: The presence of medical and midwifery problems in the current pregnancy, the presence of contraindications for the use of Entonox and back massage.

##### Intervention groups

Intervention group 1: In the back massage group, the massage technique will be massage with both hands from the T10 to S4 vertebra in a rhythmic, regular and ascending manner using the deep stroking method and return to the first place by surface stroking method, in 3 times of 15 minutes and during three periods of dilation 4-5, 6-7 and 8-9 cm during contractions. Intervention group 2: In the Entonox group, gas inhalation by the mother in a self-controlled manner, during dilatation of 4 to 10 cm, starts as soon as the abdomen tightens and stops after the end of the pain. Control group: Since no pain reduction method is routinely performed for mothers in the intended maternity hospital, the control group will not receive any intervention, but they will receive psychological support, similar to the other two

groups.

##### Main outcome variables

labor pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230610058445N1**

Registration date: **2023-08-04, 1402/05/13**

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

Last update: **2023-08-04, 1402/05/13**

Update count: **0**

##### Registration date

2023-08-04, 1402/05/13

##### Registrant information

##### Name

Zahra Khodarahmi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3623 4863

##### Email address

masoodi.m@lums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2023-09-11, 1402/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The comparison of the effect of Entonox gas and Back massage on Labor pain in Pregnant Women

**Public title**  
The comparison of the effect of Entonox gas and Back massage on Labor pain in Pregnant Women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Mother's desire to vaginal delivery A single fetus with a view of the apex of the head Gestational age Between 37 to 41 weeks The regularity of the fetal heartbeat with a number of 120-160 beats per minute The mother's vital signs are normal having minimum reading and writing literacy Dilatation 4-5 cm Having at least 2 to 3 spontaneous uterine contractions lasting 40-45 seconds within ten minutes Having less than 4 vaginal deliveries Body mass index 20-30 kg/m<sup>2</sup> The fit of the fetal head with the mother's pelvis based on clinical examination The estimated weight of the fetus 2500-4000 grams Proportionality of uterine height with gestational age in clinical examination The normality of the number of fetal movements according to the mother's report or the reaction of the result of the non stress test Mother's age between 18-35 years  
**Exclusion criteria:**  
The presence of medical and obstetrical problems in the current pregnancy Addiction to tobacco, drugs and alcohol drinks Height less than 145 cm The existence of any obstacles to vaginal delivery Existence of maternal or fetal risk factors The existence of contraindications for back massage (lumbar disc herniation, skin diseases, fever, etc.) The existence of contraindications to the use of Entonox (mother's inability to hold the mask, maxilla and facial fractures, impaired consciousness and intoxication, impaired oxygen supply, upper respiratory tract infection or respiratory disease, nasal deviation, chronic obstructive pulmonary disease, receiving large amounts of intravenous narcotics, vitamin B12 deficiency and mothers treated with vitamin B12, maxillofacial surgery in the last month, inner ear obstruction, fetal distress, unstable hemodynamic status, some heart diseases such as pulmonary hypertension, problematic airway, fullness of the mother's stomach and schizophrenia)

**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: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**  
The sampling method will be accessible and based on the Inclusion criteria. In this way, after obtaining written consent from the samples, people are assigned to groups by block randomization. Entry of people into each of the groups is done according to the number of the selected blocks and the arrangement inside the block. At first, we divide the samples into two categories: primiparous and multiparous, Then, based on the sample size, we evaluate all possible modes of block formation. as regards that the sample size is 84 people and the number of groups is 3, we will have 42 primiparous mothers and 42 multiparous mothers. So we will have 14 blocks of 6, 7 blocks for primiparous and 7 blocks for multiparous. The randomization tool will be the Random Allocation Software.

**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 Lorestan University of Medical Sciences  
**Street address**  
Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaei Sq, Moalem Ave  
**City**  
Khoram abad  
**Province**  
Lorestan  
**Postal code**  
6813833946

**Approval date**  
2023-05-24, 1402/03/03

**Ethics committee reference number**  
IR.LUMS.REC.1402.096

**Health conditions studied**

**1**

**Description of health condition studied**  
Labor pain

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

Labor pain

#### Timepoint

Measurement of pain at the beginning of the study (before the intervention) and in the dilation of 4-5, 6-7 and 8-9 cm during the intervention.

#### Method of measurement

Visual analog scale (VAS)

## Secondary outcomes

### 1

#### Description

The rate of changes in the mother's heart rate

#### Timepoint

Once before the intervention and then at 4-5, 6-7 and 8-9 cm dilation during the intervention.

#### Method of measurement

Contec pulse oximetry model CMS50D

### 2

#### Description

The amount of changes in the mother's blood oxygen saturation percentage

#### Timepoint

Once before the intervention and then at 4-5, 6-7 and 8-9 cm dilation during the intervention.

#### Method of measurement

Contec pulse oximetry model CMS50D

## Intervention groups

### 1

#### Description

Control group: Since no pain reduction method is routinely performed for mothers in the intended maternity hospital, the control group will not receive any intervention, but they will receive psychological support, similar to the other two groups. If the mother requests to receive the pain reduction method, these people will be excluded from the study.

#### Category

Other

### 2

#### Description

"Intervention group 1": In the back massage group, the massage technique will be massage with both hands from the T10 to S4 vertebra in a rhythmic, regular and ascending manner using the deep stroking method (deep pressure on the layers of the skin, muscles, fascia and tissue binder) and return to the first place by surface stroking method (soft pressure on the skin and its surrounding layers), in 3 times of 15 minutes and during

three periods of dilation 4-5, 6-7 and 8-9 cm during contractions. Vaseline will be used to reduce the friction between the hand and the skin of the mother's back during the massage. The position of the mother while receiving the massage will be lying on the left side for all samples.

#### Category

Other

### 3

#### Description

"Intervention group 2": In the Entonox group, gas inhalation by the mother in a self-controlled manner, during dilatation of 4 to 10 cm, starts as soon as the abdomen tightens (about 30 or 40 seconds before the onset of pain) and stops after the end of the pain (the mask is removed). The combination of nitrous oxide gas (N<sub>2</sub>O) or laughing gas with equal amounts of oxygen in a chamber is called Entonox. Entonox capsule should be placed in a vertical position and turned several times before use; Because nitrogen oxide is heavier than oxygen and the gases must be mixed well. The mask must be the size of the mother's face and must be firmly attached to the mother's face; also, proper ventilation should be established to prevent the remaining of the released gases in the environment.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Hadi maternity hospital in Shushtar city

##### Full name of responsible person

Zahra Khodarahmi

##### Street address

Al-Hadi Hospital, Kamarbandi St., Shahid Rajaei West Crossroads

##### City

Shushtar

##### Province

Khouzestan

##### Postal code

6451759788

##### Phone

+98 61 3623 4863

##### Email

Zhrakh77@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khoram-Abad University of Medical Sciences

##### Full name of responsible person

Bahram Rasoulian

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Lorestan University of Medical Sciences, Shahid  
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**Email**

bahramrasoulia@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Khoram-Abad 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**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Mozhgan Masoodi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Person responsible for updating data****Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to

make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available