

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Inhaled Entonox on Pain in Pregnant Mothers

#### Protocol summary

##### Study aim

The Effect of Inhaled Entonox on Pain in Pregnant Mothers

##### Design

A clinical trial with a control group, with parallel groups, one-sided, randomized, on 108 patients. Excel software rand function was used for randomization.

##### Settings and conduct

The study is a one-blind randomized clinical trial on 108 pregnant women volunteering for natural childbirth referred to Imam Khomeini Hospital in Ahvaz. Sampling will be done randomly and after obtaining the consent of pregnant women and their husbands, 54 people in the intervention group (Entonox inhalation) and 54 people in the control group (oxygen inhalation) will be included in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include primiparous, full-term and single pregnancy without any medical or obstetric complications and no prohibition of Entonox inhalation, and exclusion criteria include the occurrence of any complications during labor and delivery and the need to induce labor and cesarean section. , Will need to receive additional housing, housing during the last 8 hours or the mother's subsequent dissatisfaction for any reason.

##### Intervention groups

54 people enter the intervention group and receive Entonox (a combination of oxygen and nitrogen). 54 people enter the control group and receive only oxygen.

##### Main outcome variables

Age ; Body mass; Severity of labor pain; Duration of active phase and second phase of labor; Apgar score of the first and fifth minutes; Race and ethnicity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200815048415N1**

Registration date: **2020-11-01, 1399/08/11**

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

Last update: **2020-11-01, 1399/08/11**

Update count: **0**

##### Registration date

2020-11-01, 1399/08/11

##### Registrant information

###### Name

Parisa Niknezhad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5353 0964

###### Email address

parisaniknezhad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-06, 1399/07/15

##### Expected recruitment end date

2021-02-03, 1399/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Inhaled Entonox on Pain in Pregnant Mothers

##### Public title

The Effect of Inhaled Entonox on Pain in Pregnant Mothers

##### Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Pregnant women Normal vaginal delivery First Pregnancy Term Pregnancy Single Pregnancy Satisfaction of the volunteer and the volunteer spouse

### Exclusion criteria:

Having any medical or obstetric complications No ban on inhaling Entonox Get Extra analgesic dose Receive analgesic dose in the last eight hours Any complication during labor and the need to induce labor

## Age

No age limit

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **108**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Excel software rand function was used for randomization.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

After explaining the study to the participant and obtaining her informed consent, the participant is placed in one of the two intervention or control groups, but has no information about the type of drug received.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

##### Street address

Jondishapur University of Medical Sciences, No 1 Esfand, Golestan Blvd,

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

1579461357

#### Approval date

2020-04-13, 1399/01/25

## Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.005

## Health conditions studied

### 1

#### Description of health condition studied

Normal delivery

#### ICD-10 code

O80.8

#### ICD-10 code description

Other Single spontaneous delivery

## Primary outcomes

### 1

#### Description

Pain of delivery

#### Timepoint

One hour after delivery

#### Method of measurement

Visual scale of pain (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the first group, women will be taught to inhale Entonox gas using a mask by placing their hands on their abdomen and touching or feeling uterine contractions, and in the interval between uterine contractions. Set aside. Entonox gas is a mixture of 50% oxygen + 50% N2O

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Oxygen use Patients were instructed to apply an oxygen-containing mask to the nose and breathe in it as soon as uterine contractions began, and to continue to do so until the uterine contractions were complete. This continues from 4-5 cm dilatation of the cervix to complete dilatation. Oxygen is 100% oxygen

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahvaz Imam Khomeini Hospital

**Full name of responsible person**

Parisa Niknezhad

**Street address**

Imam Khomeini Educational and Medical Center,  
Azadegan St., Ahvaz Town

**City**

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**Postal code**

6193673111

**Phone**

+98 61 3222 2114

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himam@ajums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehdi Ahmadi Moghadam

**Street address**

Jondishapur University of Medical Sciences, No 1  
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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**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Artadokht khoshoei

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

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Assistant Professor

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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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