

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of the effects of ENTONOX inhalation and regional anesthesia on labor pain reduction in vaginal delivery

#### Protocol summary

##### Study aim

Determination of the effects of Entonox inhalation gas in comparison with local anesthesia in labor pain reduction in vaginal delivery

##### Design

Clinical trial with control group, with parallel groups, phase 2 per 100 patients

##### Settings and conduct

This study was performed in Khatam Al-Anbia Hospital in Shahroud. Group A patients were instructed to apply the Entonox mask firmly on the face and breathe in it. Entonox gas is a mixture of 50% oxygen + 50% N2O. In group B mothers, local anesthesia by injecting 25 micrograms of fentanyl with needle number 27 in the L4-L3 area will be done. In group C, no anesthesia is used and the mother will give birth naturally.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: single term pregnancy, cephalic presentation, no problem in fetus descending. Exclusion criteria include: People with asthma, high blood pressure, diabetes, any signs of fetal distress and fetal death, Any type of vaginal bleeding is more than a sign of childbirth and having placenta previa, having an infection at the injection site, coagulation diseases, Symptoms of cerebral hypertension include having contraindications to inhaling Entonox gas such as severe headache, dyspnea, asthma, emphysema, ileus

##### Intervention groups

Group (Group A) There are people who will receive Entonox during the active phase of labor and group (B) are those who are under anesthesia. They will be placed spinally for delivery and the third group (group C) women who will not receive any anesthesia.

##### Main outcome variables

Reduce labor pain in vaginal delivery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201219049769N1**  
Registration date: **2021-01-03, 1399/10/14**  
Registration timing: **retrospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

##### Registration date

2021-01-03, 1399/10/14

##### Registrant information

##### Name

Najib Farrokhy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 8670 5503

##### Email address

najibfarokhi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-23, 1398/11/03

##### Expected recruitment end date

2020-12-30, 1399/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of ENTONOX inhalation and regional anesthesia on labor pain reduction in vaginal delivery

**Public title**

Evaluation of the effects of Entonox and local anesthesia in painless delivery

**Purpose**

Supportive

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

Single term pregnancy Cephalic presentation No problem in descending of fetus

**Exclusion criteria:**

Asthma Hypertension Diabetes Melitus Fetal distress and death Massive vaginal bleeding Placenta previa Infection in sight of injection Coagulopathy Severe headache  
Dyspnea

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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 Islamic Azad University-Shahrood branch

**Street address**

Khatamolanbia Hospital, Tehran Ave

**City**

Shahrood

**Province**

Semnan

**Postal code**

3619688593

**Approval date**

2020-08-02, 1399/05/12

**Ethics committee reference number**

IR.IAU.SHAHROOD.REC.1399.013

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

Painless delivery

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

Analgesic rate based on Visual Analogue Scale

**Timepoint**

Group A once before inhalation of Entonox and once after 4 inhalations and group B before anesthesia and 5 minutes after anesthesia

**Method of measurement**

Visual Analogue Scale will be used to measure pain

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: Patients in this group were instructed to apply the Entonox mask firmly on the face and breathe in it as soon as uterine contractions begin, and continue to do so until the end of uterine contractions, leaving the uterine contractions in between. This continues from 5 to 4 cm dilatation of the cervix to complete dilatation. Entonox gas is a mixture of 50% oxygen + 50% N2O. Intervention group 2: Patients in this group will be injected with 25 micrograms of fentanyl with needle number 27 for local anesthesia in the L3-L4 or L4-L5 area.

**Category**

Rehabilitation

**2****Description**

Intervention group 2: Patients in this group will be injected with 25 micrograms of fentanyl with needle number 27 for local anesthesia in the L3-L4 or L4-L5 area.

**Category**

Rehabilitation

**3****Description**

Control group: In this group, no anesthetic will be used and patients will give birth naturally.

**Category**

Rehabilitation

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Khatamolanbia hospital  
**Full name of responsible person**  
Yousef kolookhy  
**Street address**  
Khatamolanbia hospital, Tehran Ave  
**City**  
Shahrood  
**Province**  
Semnan  
**Postal code**  
3614871151  
**Phone**  
+98 23 3239 2661  
**Email**  
najibfarokhi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Behrooz Yahyaie  
**Street address**  
Khatamolanbia Hospital, Tehran Ave  
**City**  
Shahrood  
**Province**  
Semnan  
**Postal code**  
3614871151  
**Phone**  
+98 23 3239 0360  
**Email**  
behroozyahyaie@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Islamic Azad University  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**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**  
Islamic Azad University  
**Full name of responsible person**  
Yousf kolookhy  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Khatamolanbia hospital, Tehran Ave  
**City**  
Shahrood  
**Province**  
Semnan  
**Postal code**  
3614871151  
**Phone**  
+98 23 3239 2661  
**Email**  
najibfarokhi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Yousef kolookhy  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Khatamolanbia hospital, Tehran Ave  
**City**  
Shahrood  
**Province**  
Semnan  
**Postal code**  
3614871151  
**Phone**  
+98 23 3239 2661  
**Email**  
najibfarokhi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Najib Farokhy  
**Position**  
Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Alghadir Ave, Edalat Blvd

**City**

Shahrood

**Province**

Semnan

**Postal code**

3619688593

**Phone**

+98 23 5678 7426

**Email**

najibfarokhi@gmail.com

**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