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 decending 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 placentaprevia, 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

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Iran (Islamic Republic of)

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+98 23 8670 5503

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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 decending of fetus
Exclusion criteria:
Asthma Hypertension Diabetes Melitus Fetal distres 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 Univrsity-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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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Person responsible for updating data

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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