

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of analgesic effect of inhaling Entonox alone and in combination with dexamethasone in labor

#### Protocol summary

##### Summary

Objective: Comparison of analgesic effect of inhaling Entonox alone and in combination with dexamethasone in labor. Design: In this interventional study, 90 pregnant women who are candidates for natural childbirth will be selected and divided into two groups using block randomization method (n=45 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen. Inclusion criteria: Over 37 weeks pregnancy, first or second pregnancy and singleton. Exclusion criteria: Malpresentation of fetus and Macrosomia. Setting and intervention: Upon starting the active phase of labor first group will receive face mask of entonox at the beginning of uterine contractions and continue deep inspirations in times when there is pain and cramps and the placebo (Distilled water, 2 cc, Irandaroo Co., once) will be administered intravenously. The second group will receive Entonox (like the first group) with 8mg intravenous dexamethasone (once, 2 cc, Irandaroo Co.) injection. Outcomes measure: Parturient pain score will evaluate according to the VAS score once before any analgesic administrations and two times after (30 and 60 min) analgesic administrations using a structured questionnaire and a subjective labor pain scale (visual analogue scale). Also appgar scores at 1 and 5 minutes will record using a appgar test questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012323559N8**  
Registration date: **2017-03-24, 1396/01/04**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-03-24, 1396/01/04

##### Registrant information

###### Name

Somaieh Matin

###### Name of organization / entity

Ardabil University of Medicine Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3373 3011

###### Email address

s.matin@arums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of analgesic effect of inhaling Entonox alone and in combination with dexamethasone in labor

##### Public title

Labor pain relief with Entonox

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Over 37 weeks pregnancy, first or

second pregnancy, singleton. Exclusion criteria:  
Malpresentation of fetus, Macrosomia.

**Age**

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ardabil University of Medical Sciences

**Street address**

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

**City**

Ardabil

**Postal code**

5615783134

**Approval date**

2016-12-21, 1395/10/01

**Ethics committee reference number**

IR.ARUMS.REC.1395.90

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

Labor pain

**ICD-10 code**

O80, O84

**ICD-10 code description**

Delivery

**Primary outcomes****1****Description**

pain

**Timepoint**

Before analgesic administrations and two times (30 and 60 min) after intervention

**Method of measurement**

Visual analog scale

**Secondary outcomes****1****Description**

Apgar

**Timepoint**

1 and 5 minutes after birth

**Method of measurement**

Apgar test

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

Face mask of entonox at the beginning of uterine contractions and continue deep inspirations in times when there is pain and cramps and intravenous placebo (Distilled water, 2 cc, Irandaroo Co., once)

**Category**

Treatment - Drugs

**2****Description**

Face mask of entonox at the beginning of uterine contractions and continue deep inspirations in times when there is pain and cramps and 8mg intravenous dexamethasone (2 cc, IrandarooCo., once)

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alavi Hospital

**Full name of responsible person**

Dr. Fatemeh Hashemi

**Street address**

Alavi Hospital, Moadi street, Ardabil

**City**

Ardabil

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Shahram Habibzadeh

**Street address**

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

**City**

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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**

Vice chancellor for research, Ardabil University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr. Fateme Hashemi

**Position**

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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*