

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of analgesic effect of inhaling Entonox with and without paracetamol in labor

#### Protocol summary

##### Study aim

Evaluation of the efficacy of Entonox inhalation alone and in combination with paracetamol in controlling normal labor pain

##### Design

Group A (50 cases) will receive intravenous paracetamol at a dose of 1 gram and Entonox inhalation, and Group B (50 cases) will receive normal saline (50 cases) and Entonox inhalation. Patients undergo continuous pulse oximetry and FHR monitoring.

##### Settings and conduct

Questionnaire included age, weight, maternity records, type of analgesia, fetal heart rate, duration of active phase of labor, duration and intervals of uterine contractions, neonatal apgar score at first and fifth minutes, pain score before and after analgesia and The side effects in each case will be completed by the female resident. Patients' vital signs, including blood pressure, heart rate and respiratory rate before and after analgesia, and visual analogue score (VAS) were measured every 30 minutes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Single pregnancy (41 - 37 weeks) - Onset of active phase of labor - Cephalic presentation - Absence of fever or serious systemic disease - Absence of fetal distress - Absence of meconium  
Exclusion criteria: Existence of fetal distress - presence of meconium

##### Intervention groups

The group will be anesthetized by intravenous paracetamol injections of 1 g and inhaled Entonox.

##### Main outcome variables

Score pain before and after prolonged analgesia and uterine contractions intervals, first and fifth minute neonatal apgar score,

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190915044779N1**  
Registration date: **2019-09-30, 1398/07/08**  
Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

##### Registration date

2019-09-30, 1398/07/08

##### Registrant information

###### Name

Rogayye Dargahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3323 0739

###### Email address

z.noori@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

2018-09-23, 1397/07/01

##### Actual recruitment end date

2019-03-20, 1397/12/29

##### Trial completion date

2019-03-20, 1397/12/29

##### Scientific title

Comparison of analgesic effect of inhaling Entonox with and without paracetamol in labor

## Public title

Comparison of analgesic effect of inhaling Entonox with and without paracetamol in labor

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Single pregnancy (41 - 37 weeks) Onset of active phase of labor Cephalic presentation Absence of fever or serious systemic disease Absence of fetal distress Absence of meconium Age 14 to 40 years

### Exclusion criteria:

Pregnancy hypertension Gestational diabetes

## Age

From **14 years** old to **40 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

Actual sample size reached: **100**

## 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 Ardabil University of Medical Sciences

##### Street address

No. 1, Moallem Ave

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5613843785

#### Approval date

2018-08-31, 1397/06/09

#### Ethics committee reference number

IR.ARUMS.REC.1397.069

## Health conditions studied

### 1

#### Description of health condition studied

Labor pain

#### ICD-10 code

O47.0

#### ICD-10 code description

False labor before 37 completed weeks of gestation

## Primary outcomes

### 1

#### Description

The main outcome variable in this study is pain.

#### Timepoint

The beginning of the delivery process and then every 30 minutes until delivery is complete.

#### Method of measurement

The VAS is a pain measurement scale in which a person scores from 0 to 10. 0 means no pain and 10 means the worst pain one can imagine.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The group will be anesthetized by intravenous paracetamol injections of 1 gr and inhaled Entonox.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The group will receive intravenous administration of normal saline and inhaled Entonox.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alavi hospital

##### Full name of responsible person

Zahra Noori

##### Street address

No. 1, Moallem Ave

##### City

Ardabil

##### Province

Ardabil  
**Postal code**  
5613843793  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Parvane Naftchi  
**Street address**  
No. 1, Moallem Ave  
**City**  
Ardabil  
**Province**  
Ardabil  
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**Email**  
meisamfooladi@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ardabil 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**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Rogayye Dargahi  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Rogayye Dargahi  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Ardabil University of Medical Sciences  
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Rogayye Dargahi  
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**Latest degree**  
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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Questionnaires and case number will be provided to the university research unit. And the SPSS file will be published.

**When the data will become available and for how long**

Immediately upon completion of thesis

**To whom data/document is available**

University professors

**Under which criteria data/document could be used**

The information will be anonymous to protect patients' privacy.

**From where data/document is obtainable**

Contact Dr. Dargahi's Email.

**What processes are involved for a request to access data/document**

Request via email to Dr. Dargahi then confirmation from Ms. Parvaneh Naftchi (Thesis Officer of Ardabil University of Medical Sciences)

**Comments**