

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison effect of Entonox and Dexamethasone versus Remifentanil and Dexamethasone on the control of painless delivery

#### Protocol summary

##### Study aim

Efficacy of Entonox and Dexamethasone with Remifentanil and Dexamethasone in Controlled Pain.

##### Design

Control group clinical trial, with parallel, double-blind, randomized groups.

##### Settings and conduct

Ardebil Alavi Hospital

##### Participants/Inclusion and exclusion criteria

The study participants were the first pregnant mothers.

##### Intervention groups

In this study, 100 pregnant women were randomly assigned into A and B groups among first pregnant women referred to Hospital.

##### Main outcome variables

Promote painless delivery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190924044865N1**

Registration date: **2019-12-30, 1398/10/09**

Registration timing: **retrospective**

Last update: **2019-12-30, 1398/10/09**

Update count: **0**

##### Registration date

2019-12-30, 1398/10/09

##### Registrant information

##### Name

Zahra Asdagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 937 688 4241

##### Email address

zahra.asdagh@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-09-22, 1398/06/31

##### Expected recruitment end date

2019-12-20, 1398/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of Entonox and Dexamethasone versus Remifentanil and Dexamethasone on the control of painless delivery

##### Public title

Comparison effect of Entonox and Dexamethasone

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

First Pregnancy Term pregnancy Without illness

##### Exclusion criteria:

preterm labor multipar

##### Age

No age limit

##### Gender

Female

##### Phase

3

##### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The randomization method is randomized blocking. Patients in groups A and B are placed in quadratic blocks (two patients in group A and two patients in group B). There will be a draw and the blocks will continue to be completed until the number of samples is 100.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

Participants, clinical outcome evaluator caregivers are kept blind. And they have no information about whether or not to take the medicine.

### 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

Shahid Motahari Street, Alavi Hospital

##### City

Ardebil

##### Province

Ardabil

##### Postal code

۵۶۱۸۹۸۵۹۹۱

#### Approval date

2019-06-22, 1398/04/01

#### Ethics committee reference number

IR.ARUMS.REC.1398.248

## Health conditions studied

### 1

#### Description of health condition studied

Painful delivery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain score

#### Timepoint

30, 60, 120, 180 minutes

#### Method of measurement

Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group (A): This group includes pregnant women receiving entonox and dexamethasone. In this group, after reaching the active phase of labor, the patient is advised to inhale one or two puffs of Entonex gas by mask each time he / she is given 8 mg of dexamethasone at the same time as Entonex gas.

#### Category

Treatment - Drugs

### 2

#### Description

Second Intervention Group (B): This group includes pregnant women receiving remifentanil and dexamethasone. In this group, after reaching the active phase of delivery, dexamethasone is administered 8 mg intravenously, along with remifentanyl opioid administered by the pain pump at a concentration of 1.5 mg per 100 ml serum at 14 cc / h. Starts.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alavi Hospital

##### Full name of responsible person

Giti Rahimi

##### Street address

Shahid Motahari Street

##### City

Ardebil

##### Province

Ardabil

##### Postal code

5613974156

##### Phone

+98 45 3324 8888

##### Email

zahra.asdagh@gmail.com

## Sponsors / Funding sources

**1**

### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

شهاب بهلولی

**Street address**

Shahid Motahhari Street, Alavi Hospital

**City**

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**Province**

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**Postal code**

5613974156

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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**

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**

Zahra Asdagh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

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Specialist

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## Person responsible for updating data

### Contact

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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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