

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The comparison of the Effect of inhaled entonox with and without spinal anesthesia on outcomes painless delivery

#### Protocol summary

##### Summary

Objectives: To determine the effect of inhaled entonox with and without spinal anesthesia on maternal and neonate outcomes in vaginal delivery. Study design: After obtaining informed consent of seventy five primigravid parturients requesting to select one of the following three methods during labor in vaginal delivery. Inhale entonox gas, entonox with spinal analgesia or non-analgesia labor. Setting and conduct: Parturients in the first group receive the entonox gas by commencement of active phase with cervix dilatation 3-4cm until 9-10 cm. Second group, receive the entonox with cervix dilatation 3-4cm until 5-6cm and then entonox is interrupted and they receive spinal anesthesia. Third group do not receive any analgesia treatment during labor. Participants including major eligibility criteria: The inclusion criteria including aged between 18 and 35; primigravid with pregnancy  $\geq 37$  weeks gestation; in the active phase of labor with cervical dilation of 3-4 cm. Exclusion criteria including contraindication for vaginal delivery or spinal analgesia; multiple pregnancies; use of sedative drugs; pregnancy related disease and fetal malpresentation. Intervention: Parturients in the first group received entonox and in the second group received entonox and then intrathecal injection of 0.2 ml of bupivacaine (10 mg) plus 0.2 ml meperidine at L4-L5. Third group don't receive analgesia treatment. Main outcome measures (variables): Duration of the first, second and third stage of labor, perineal laceration, labor pain, maternal blood pressure, birth weight and Apgar scores were recorded and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111218109N2**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-29, 1395/03/09

##### Registrant information

###### Name

Hamdollah Delaviz

###### Name of organization / entity

Yasuj University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 2223 5135

###### Email address

delaviz.h@yums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Yasuj University of Merical Sciences, Vice chancellor for research

##### Expected recruitment start date

2015-04-03, 1394/01/14

##### Expected recruitment end date

2017-04-03, 1396/01/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of the Effect of inhaled entonox with and without spinal anesthesia on outcomes painless delivery

##### Public title

Delivery

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

The inclusion criteria including aged between 18 and 35; primigravid with pregnancy  $\geq 37$  weeks gestation; in the active phase of labor with cervical dilation of 3-4 cm. Exclusion criteria including contraindication for vaginal delivery or spinal analgesia; multiple pregnancies; use of sedative drugs; pregnancy related disease and fetal malpresentation.

## **Age**

From **18 years** old to **35 years** old

## **Gender**

Female

## **Phase**

3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **75**

## **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**

Biomedical research ethics committees in Yasuj  
University of Medical Science

##### **Street address**

Vice chancellor for research, Yasuj University of  
Medical Sciences, Mothari street

##### **City**

Yasuj

##### **Postal code**

7591994799

#### **Approval date**

2015-04-03, 1394/01/14

#### **Ethics committee reference number**

ir.yums.REC.1394.34

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

labour and childbirth

#### **ICD-10 code**

080-084, O

#### **ICD-10 code description**

delivery, Pregnancy, childbirth and the puerperium,  
prolong first stage of labour, prolong second stage of  
labour

## **Primary outcomes**

### **1**

#### **Description**

Duration of the first, second and third stage of labor

#### **Timepoint**

labor

#### **Method of measurement**

chronometer

### **2**

#### **Description**

perineal laceration

#### **Timepoint**

after delivery

#### **Method of measurement**

examination

### **3**

#### **Description**

fetal heart rate

#### **Timepoint**

fetal heart rate will record in every 15 and 5 minutes in  
the first and second stage of labor

#### **Method of measurement**

sonicaid

### **4**

#### **Description**

Apgar scores

#### **Timepoint**

Apgar score will record in first minute and 5 minute after  
delivery.

#### **Method of measurement**

examination

### **5**

#### **Description**

birth weight

#### **Timepoint**

after delivery

#### **Method of measurement**

balance

### **6**

#### **Description**

labor pain

#### **Timepoint**

during labor

#### **Method of measurement**

visual analog scale pain

## 7

### Description

maternal blood pressure

### Timepoint

blood pressure will measure before delivery and in every 15 minutes during the labor

### Method of measurement

manometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In first group the parturients train to breathing deep entonox gas (nitrous oxide and oxygen, N<sub>2</sub>O+O<sub>2</sub>) in mask whenever she touch or feel uterine contractions by put their hand on abdomen and put mask aside between uterine contractions. They use of entonox with cervix dilatation 3-4cm and effacement  $\geq 40\%$  and put aside at 9-10 cm dilatation with effacement  $\geq 80\%$ .

#### Category

Treatment - Other

### 2

#### Description

Second group receive entonox inhalation by commencement of active phase with cervix dilatation 3-4cm until 5-6 cm and then entonox will interrupted and they receive 500 ml ringer lactate. For achieving spinal analgesia, the intervertebral space of L4-L5 will identify and intrathecal injection dose including 0.2 ml of bupivacaine (10 mg) plus 0.2 ml mepridine (10mg) in two stages with using of spinal needle (27-gauge). In the first stage a third of this compound was injected and the remaining two-thirds will inject 5 minutes later.

#### Category

Treatment - Drugs

### 3

#### Description

Third group do not receive any analgesia treatment during labor

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam sajad hospital

##### Full name of responsible person

Parastou Rad

##### Street address

Imam Sajad hospital, Jalil Street

##### City

Yasuj

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Yasuj University of Medical Sciences

##### Full name of responsible person

Abdmohammad Mosavi

##### Street address

Vice chancellor for research of Yasuj University of Medical Sciences, Yasuj university of Medical sciences, Mothari street

##### City

Yasuj

##### Grant name

مقایسه تاثیر روش استنشاقی انتونوکس با و بدون بی حسی نخاعی در پیامد های زایمان بی درد

##### Grant code / Reference number

ir.yums.REC.1394.34

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Vice chancellor for research of Yasuj 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

Yasuj university of Medical sciences,

##### Full name of responsible person

Hamdollah Delaviz

##### Position

Associate professor of Anatomy

##### Other areas of specialty/work

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www.yums.ac.ir

## 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*