

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The comparison of the effect of Tens and Entonox gas on pain control in Primigravida

#### Protocol summary

##### Study aim

Comparison of Trans-cutaneous electrical nerve stimulation (TENS) and Entonox on pain control during delivery

##### Design

A randomized clinical trials with control group, community and performance based with parallel group design, and 40 subjects in each group.

##### Settings and conduct

This study was a randomized clinical trial with three groups that was performed at the maternity ward of Ayatollah Mousavi Hospital in Zanjan. In this study, the patient was aware of the method of analgesia. Therefore, Blinding was not done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparity; Pregnant mothers aged 45-15 years old; Gestational age more than 37 weeks; Single pregnancy; The onset of active phase of labor.  
Exclude criteria: Need to emergency cesarean section

##### Intervention groups

Intervention group 1: the effect of TENS on labor pain. In the TENS group, mother can change the frequency of the device from low (at least pain relief) to high (maximum pain relief). Intervention group 2: the effect of Entonox gas on delivery pain. In the Entonox group, the patient with a deep inhalation, a pause at the end of the inhalation, a slow exhalation, and then a rest continues gas inhalation. At the end of the uterine contraction, she will stop the gas inhalation and will inhale the room air.  
Control group: without any intervention

##### Main outcome variables

Pain score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180707040370N4**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **retrospective**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

##### Registration date

2019-03-26, 1398/01/06

##### Registrant information

###### Name

Ensiyeh Jenabi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0496

###### Email address

e.jenabi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-10-12, 1396/07/20

##### Expected recruitment end date

2018-01-10, 1396/10/20

##### Actual recruitment start date

2017-10-12, 1396/07/20

##### Actual recruitment end date

2018-01-10, 1396/10/20

##### Trial completion date

2018-02-19, 1396/11/30

##### Scientific title

The comparison of the effect of Tens and Entonox gas on pain control in Primigravida

##### Public title

The effect of Trans-cutaneous electrical nerve stimulation (TENS) and Entonox gas on labor pain control

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Nulliparity Being at the age of 15-45 years old Gestational age more than 37 weeks Singleton pregnancy Beginning of the active phase of delivery

### Exclusion criteria:

Need to emergency cesarean section

## Age

From **15 years** old to **45 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

Actual sample size reached: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants were randomly assigned to the three groups of 40 recipients of TENS and Entonox gas and other group without any intervention using the Select (randbetween (1; 2)) command, in the Excel computer program.

## 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 Zanjan University of Medical Sciences

##### Street address

Zanjan University of Medical Sciences, Azadi Blvd

##### City

Zanjan

##### Province

Hamadan

##### Postal code

4515613191

#### Approval date

2016-08-09, 1395/05/19

#### Ethics committee reference number

ZUMS.REC.1395.147

## Health conditions studied

### 1

#### Description of health condition studied

The comparison of TENS and Entonox on delivery pain

#### ICD-10 code

O63

#### ICD-10 code description

Long labor

## Primary outcomes

### 1

#### Description

Pain score

#### Timepoint

At the beginning of the study and at dilatations of 4-6, 6-8, 8-10 cm

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: the effect of TENS on labor pain. In the TENS group, first place the electrodes at the appropriate place behind the patient. The electrodes are parallel to the spine. The first pair of electrodes is placed between the tenth thoracic and the first lumbar vertebra. The second pair of electrodes is placed between the second to fourth sacral vertebrae. Then, mother can change the frequency of the device from low (at least pain relief) to high (maximum pain relief).

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: the effect of Entonox gas on delivery pain. In the Entonox group, we first teach to the patient how to use Entonox gas. Gas usage should begin at the beginning of uterine contraction. The capsule should be shaken before use. Gas inhalation will be continued with a deep inhalation, a pause at the end and a rest phase. By the of uterine contraction, the gas inhalation will be stopped and the patient will use the room air. We will stop using Entonox when the patient won't cooperate or the level of the patient's consciousness will be decreased.

#### Category

Treatment - Drugs

### 3

**Description**

Control group: without any intervention

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Maternity ward of Mousavi Hospital in Zanjan

**Full name of responsible person**

Behnaz Molaei

**Street address**

Mousavi Hospital, Gavazang Ave

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3313 0001

**Email**

molaei@zums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Alireza Shoghli

**Street address**

Zanjan University of Medical Sciences, Azadi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3342 0677

**Email**

shoghli@zums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Behnaz Molaei

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Zanjan University of Medical Sciences, Azadi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3342 0677

**Email**

molaei@zums.ac.ir

## Person responsible for scientific inquiries

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Behnaz Molaei

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Zanjan University of Medical Sciences, Azadi Blvd

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3342 0677

**Email**

molaei@zums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

انسبیه جنابی

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

خیابان شهید فهمیده، دانشگاه علوم پزشکی همدان

**City**

Hamadan

**Province**

Hamadan

**Postal code**

65178

**Phone**

+98 81 3838 0150

**Email**

en.jenabi@yahoo.com

## Sharing plan

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

Yes - There is 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

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

A portion of the information, such as information on the main outcome or the like, can be shared.

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

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academia

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

Any analysis on the data is allowable with the source citation.

**From where data/document is obtainable**

Zanjan University of Medical Sciences

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

6 months after printing results

**Comments**