

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Entonox on Labor Pain and Outcome of Delivery among Primi-Parous Women Referred to Atieh Hospital in Hamadan, 2014

Protocol summary

Summary

This study aims to investigate the effectiveness of nitrous oxide on pain of labor contractions and duration of Labor. The patients will be randomized to receive either a pre-prepared mixture of nitrous oxide and oxygen or only oxygen by a coin. Study drugs will start as early as the onset of pain with each contraction. The patient herself administrate gases via a face-mask which enables the patients to breathe fresh gas in each inspiration. The gas administration will be continued to the end of contraction pain at which the patient breathed the room air. Variables such as SaO₂, blood pressure, pain, duration of labor and side effects will be record. Descriptive and interracial statistical analysis the data in the two groups will compare. Using SPSS version 16 data will analyze with $p < 0.05$.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014060210426N2**

Registration date: **2014-10-10, 1393/07/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-10, 1393/07/18

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1822 4396

Email address

parsa@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Entonox on Labor Pain and Outcome of Delivery among Primi-Parous Women Referred to Atieh Hospital in Hamadan, 2014

Public title

The Effect of Entonox on Labor Pain and Outcome of Delivery among Primi-Parous Women Referred to Atieh Hospital in Hamadan, 2014

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: full term pregnant women; single pregnancy; primiparous; aged between 18-35 years old; vertex presentation; normal pelvic and no stimulation before study. Exclusion criteria: having a systematic chronic diseases e.g. hypertension, diabetes, asthma, vaginal bleeding; twin pregnancy; multiparous and stimulation before study.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences

City

Hamadan

Postal code

Approval date

2014-09-16, 1393/06/25

Ethics committee reference number

2901/9/35/16/پ

Health conditions studied

1

Description of health condition studied

Labor

ICD-10 code

O80.0

ICD-10 code description

Single spontaneous delivery

Primary outcomes

1

Description

Relief of Labor pain

Timepoint

Initial, after one hour, after two hours, after three hours, after four hours

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Duration of labor

Timepoint

Initial, after one hour, after two hours, after three hours, after four hours

Method of measurement

Duration of labor per hour

Intervention groups

1

Description

After completing consent form by participants, The patients will be randomized to receive either a nitrous oxide (Entonox) or oxygen by a coin. In the intervention group Entonox gas will be started as early as the onset of pain with each contraction. The patient herself will administrate Entonox gas via a face-mask which enables the patients to breathe fresh gas in each inspiration. The gas administration will continue to the end of contraction pain at which the patient breathed the room air.

Variables such as SaO₂, blood pressure, pain, duration of labor and side effects will record.

Category

Treatment - Drugs

2

Description

In control group the oxygen will be started as early as the onset of pain with each contraction. The patient herself will administrate Oxygen gas via a face-mask which enables the patients to breathe fresh gas in each inspiration. The gas administration will continue to the end of contraction pain at which the patient breathed the room air. Variables such as SaO₂, blood pressure, pain, duration of labor and side effects will record.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Atyieh Hospital, Hamadan

Full name of responsible person

Parisa Parsa-Faryar Hakem Zadeh-Nafiseh Saied Zadeh

Street address

Atyieh Hospital, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Saied Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Assistant Professor PhD

Other areas of specialty/work

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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