Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Entonox on Labor Pain and Outcome of Delivery among Primi-Parrous Women Reffered 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)

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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-Parrous Women Reffered to Atieh Hospital in Hamadan, 2014

Public title

The Effect of Entonox on Labor Pain and Outcome of Delivery among Primi-Parrous Women Reffered 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
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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
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Dr. Parisa Parsa
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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