Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Entonox on normal vaginal delivery labor and maternal hemodynamic changes and fetal apgar

Protocol summary

Summary

This study is done to investigate the effect of Entonox on normal vaginal delivery labor and maternal hemodynamic changes and fetal apgar. Sixteen women candidate for normal vaginal delivery, having the inclusion criteria, will be randomly divided into 2 groups. The intervention group will receive Entonox gas while control group will not. After the active phase of delivery mothers in intervention group will receive Entonox through masks and it will be continue till the second stage. The mean of the pain and maternal hemodynamic changes during the Entonox receiving and the fetal apgar after the birth will be evaluated and will be compared with control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105176480N2**
Registration date: **2012-06-13, 1391/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-13, 1391/03/24

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellory for research, Shahrekord university of medical sciences

Expected recruitment start date

2012-06-06, 1391/03/17

Expected recruitment end date

2012-08-18, 1391/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Entonox on normal vaginal delivery labor and maternal hemodynamic changes and fetal apgar

Public title

Investigating the effect of Entonox on normal vaginal delivery labor and maternal hemodynamic changes and fetal apgar

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: primiparous women; pregnancy age of 38-42; non twin pregnancy with the cephalic view; being in the early active phase of delivery; having normal fetal heart pattern; weight between 60-80 Kgr. Exclusion criteria: having cardio and other internal disease.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahrekord university of medical sciences
Street address
Kashani Blvd.
City
Sahrekord
Postal code
Approval date
2009-05-28, 1388/03/07
Ethics committee reference number
88-3-7

Health conditions studied

1

Description of health condition studied
labor
ICD-10 code
O80
ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
labor
Timepoint
one hour
Method of measurement
NSR digital proportional measurement

2

Description
maternal respiration rate
Timepoint
one hour
Method of measurement
numeration

3

Description
maternal blood pressure
Timepoint
one hour
Method of measurement
mercurial manometer

4

Description
maternal heart rate
Timepoint
one hour
Method of measurement
using a device

Secondary outcomes

1

Description
baby apgar
Timepoint
one and five minutes after the birth
Method of measurement
related questionnare

2

Description
nausea and vomiting
Timepoint
during the delivery
Method of measurement
observation

Intervention groups

1

Description
After starting the delivery active phase (dilatation 4 cm), the intervention group will receive Entonox, with feeling the pain, mothers start to inspiration the gas, with vanishing the pain mothers stop inspiration. They will receive Entonox till the end of the second stage.
Category
Prevention

2

Description
The control group will receive oxygen gas after starting the delivery active phase (dilatation 4cm).

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital
Full name of responsible person
Dr. Sheida Shabanian
Street address
Parastar street
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellory for research, Shahrekord university of medical sciences
Full name of responsible person
Dr. Mahmoud Mobasheri
Street address
Kashani Blvd
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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
Vice chancellory for research, Shahrekord 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
Hajar hospital
Full name of responsible person
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Person responsible for updating data

Contact

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