Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Determination of side effects of entonox on mother & new born in primiparus pregnant women

Protocol summary

Summary

The aim of this study is to determine the side effects of entonox on pregnant women during labor to reduce patient demand cesarean section. This study is a single blind controlled randomized clinical trial on term primiparus pregnant women in active phase of labor without any medical disease or obstetrical complications excluded that refused to participate in study .The number of participants was 178 patients in case & control groups witch entonox & oxygen was administrated respectively. Thereafter parameters such as evidence of placental abruption before 7 after delivery, mechonium passage, APGAR score, symptoms such as nausea & vomiting ,drowsiness, vertigo, dryness of mouth & tongue paresthesia & the amount of post partum bleeding number of used pads 6 hours after delivery & drop of Hb 6 hours of delivery were investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012035299N1**
Registration date: **2011-11-04, 1390/08/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-11-04, 1390/08/13

Registrant information

Name

Seideh Saideh Asadi

Name of organization / entity

Hamedan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

s-asadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2011-01-13, 1389/10/23

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of side effects of entonox on mother & new born in primiparus pregnant women

Public title

Side effects of entonox on mother & new born

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :primiparus;term pregnancy(37-42wks);active phase of labor(cervical dilatation of 3-4 cm);no medical disease or obstetrical complication in mother & fetus Exclusion criteria :women who refuse to participate in this study

Age

No age limit

Gender

Female

Phase

N/A
Groups that have been masked
No information
Sample size
Target sample size: **178**
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
Hamedan university of medical sciences
Street address
School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street
City
ÎHamedan
Postal code
Approval date
2011-01-12, 1389/10/22
Ethics committee reference number
16/35/9/163358/پ

Health conditions studied

1

Description of health condition studied
delivery related complications
ICD-10 code
o67.8
ICD-10 code description
Excessive intrapartum haemorrhage

Primary outcomes

1

Description
placental abruption
Timepoint
during intervention
Method of measurement
observation

2

Description
accelerated labor
Timepoint
during intervention
Method of measurement
observation

3

Description
neonatal APGAR score minute 1&5
Timepoint
1&5 minutes after delivery
Method of measurement
observation

4

Description
Final route of delivery
Timepoint
during intervention
Method of measurement
observation

5

Description
fetal meconium passing
Timepoint
during intervention
Method of measurement
observation

6

Description
maternal complications
Timepoint
6 hours after delivery
Method of measurement
question sheet

7

Description
used pads
Timepoint
6 hours after itervention
Method of measurement
question sheet

8

Description
Hb
Timepoint
Before & 6 hours after intervention
Method of measurement
grams per desiliteres

Secondary outcomes

empty

Intervention groups

1

Description
In the case group entonox was administrated in active phase of labor & the patient inspirited in the mask 30 seconds before beginning of labor pain.
Category
Treatment - Drugs

2

Description
In the control group oxygen was administrated in active phase of labor.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamadan's Fatemieh Hospital
Full name of responsible person
Dr. Shahla Nasrolahi
Street address
Hamadan's Fatemieh Hospital
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan's Fatemieh Hospital delivery ward
Full name of responsible person
Dr. Shala Nasrolahi
Street address
Hamadan's Fatemieh Hospital
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan's Fatemieh Hospital delivery ward
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
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Shala Nasrolahi
Position
Associated professor
Other areas of specialty/work
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School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street
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Person responsible for scientific inquiries

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Person responsible for updating data

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Dr. Shahla Nasrolahi
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Associated professor

Other areas of specialty/work

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School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street

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Hamedan

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Fax

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Web page address

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