Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of analgesic effect of inhaling Entonox alone and in combination with dexamethasone in labor

Protocol summary

Summary

Objective: Comparison of analgesic effect of inhaling Entonox alone and in combination with dexamethasone in labor. Design: In this interventional study, 90 pregnant women who are candidates for natural childbirth will be selected and divided into two groups using block randomization method (n=45 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen. Inclusion criteria: Over 37 weeks pregnancy, first or second pregnancy and singleton. Exclusion criteria: Malpresentation of fetus and Macrosomia. Setting and intervention: Upon starting the active phase of labor first group will receive face mask of entonox at the beginning of uterine contractions and continue deep inspirations in times when there is pain and cramps and the placebo (Distilled water, 2 cc, Irandaroo Co., once) will be administered intravenously.The second group will receive Entonox (like the first group) with 8mg intravenous dexamethasone (once, 2 cc, Irandaroo Co.) injection. Outcomes measure: Parturient pain score will evaluate according to the VAS score once before any analgesic administrations and two times after (30 and 60 min) analgesic administrations using a structured questionnaire and a subjective labor pain scale (visual analogue scale). Also apgar scores at 1 and 5 minutes will record using a apgar test questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012323559N8**
Registration date: **2017-03-24, 1396/01/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-24, 1396/01/04

Registrant information

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Somaieh Matin
Name of organization / entity
Ardabil University of Medicine Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of inhaling Entonox alone and in combination with dexamethasone in labor

Public title

Labor pain relief with Entonox

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Over 37 weeks pregnancy, first or

second pregnancy, singleton. Exclusion criteria: Malpresentation of fetus، Macrosomia.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences

Street address
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City
Ardabil

Postal code
5615783134

Approval date
2016-12-21, 1395/10/01

Ethics committee reference number
IR.ARUMS.REC.1395.90

Health conditions studied

1

Description of health condition studied
Labor pain

ICD-10 code
O80, O84

ICD-10 code description
Delivery

Primary outcomes

1

Description
pain

Timepoint
Before analgesic administrations and two times (30 and 60 min) after intervention

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Apgar

Timepoint
1 and 5 minutes after birth

Method of measurement
Apgar test

Intervention groups

1

Description
Face mask of entonox at the beginning of uterine contractions and continue deep inspirations in times when there is pain and cramps and intravenous placebo (Distilled water, 2 cc, Irandaroo Co., once)

Category
Treatment - Drugs

2

Description
Face mask of entonox at the beginning of uterine contractions and continue deep inspirations in times when there is pain and cramps and 8mg intravenous dexamethasone (2 cc, IrandarooCo., once)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alavi Hospital

Full name of responsible person
Dr. Fatemeh Hashemi

Street address
Alavi Hospital, Moadi street, Ardabil

City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ardabil University of Medical Sciences
Full name of responsible person
Dr Shahram Habibzadeh
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Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran
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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 chancellor for research, Ardabil 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

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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