

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison between entonox and oxygen on lowering labor pain and the progress of labor

Protocol summary

Summary

The purpose of the present study is to compare the effect of entonox and oxygen on labor pain and labor progress. Design: A randomized clinical trial was performed on 120 nulliparas pregnant women who had been admitted in the labor ward of Akbarabadi Teaching Hospital for termination of pregnancy and labor pain in the active phase of labor. Setting and conduct: The patients were randomly assigned into the two groups of entonox (case group) and oxygen group (control group)(each groups were 60 women). Participants: Inclusion criteria include: term singleton pregnancy, cephalic presentation and appropriate pelvis. Exclusion criteria are: any systemic disorder like asthma; hypertension; diabetes; multiparity; any sign of fetal distress and fetal death; any vaginal bleeding more than labor show; and placenta previa(low risk pregnancy). Intervention: Case group (group A) were women who received entonox during active phase of labor and group B (control group) were women who received oxygen. Main outcomes: Pain was evaluated using Visual Analogue Scale(VAS). Duration of the active phase and second stage of labor and also the total duration of labor and pain and adverse effects were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207182624N9**
Registration date: **2013-01-09, 1391/10/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-09, 1391/10/20

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between entonox and oxygen on lowering labor pain and the progress of labor

Public title

lowering labor pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: term singleton pregnancy; cephalic presentation and appropriate pelvis. Exclusion criteria are: any systemic disorder like asthma; hypertension; diabetes; multiparity; any sign of fetal distress and fetal death; any vaginal bleeding more than

labor show; and placenta previa (low risk pregnancy).

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 120

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

Ethic committee of Tehran University of Medical Sciences

Street address

Keshavarze Boulevard, Ghods Cross.

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

90-7214

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

o99-o00 ,

ICD-10 code description

Pregnancy,childbirth and the puerperium, Single spontaneous delivery

Primary outcomes

1

Description

Labor pain

Timepoint

30 minutes

Method of measurement

VAS

Secondary outcomes

1

Description

duration of labor

Timepoint

From the beginning of the active phase of labor till full dilatation (active phase of the first stage) and from full dilatation (10 cm) till delivery of fetus(second stage)

Method of measurement

Minute

Intervention groups

1

Description

using entonox; the patients was taught to put the mask closely on their noses and breath continuously up to the end of uterine contraction and remove the mask between the contractions. During entonox using, it was temporarily discontinued in the occurrence of the side effects like nausea, vomiting, dizziness. This way was continued from cervical dilatation of 4-5 cm till full dilatation. Entonox is a mixture of 50% oxygen and 50% N2O.

Category

Treatment - Drugs

2

Description

using oxygen ; the patients was taught to put the mask closely on their noses as soon as contraction was begun and breath continuously up to the end of uterine contraction and remove the mask between the contractions. This way was continued from cervical dilatation of 4-5 cm till full dilatation. Oxygen is a 100% oxygen .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Teaching Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi Street, Molavi Cross.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Tehran University of Medical Sciences.

Full name of responsible person

Dr. Fotuhi

Street address

Keshavarz Boulevard , Ghods Cross.

City

Tehran

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 , Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

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Position

MD, Professor

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