Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of entonox in comparison with lidocaine on severity of pain after episiotomy in nulliparous women

Protocol summary

Summary

The aim of this study was be to assess the effects of entonox in compare with lidocaine on severity of pain during episiotomy incision and repair in nulliparous women. This randomized, single blind, comparison study was carried out in Alhadi Hospital, Shushtar, Iran. Inclusion criteria for this study included: primipara women between 39 to 42 weeks of gestation according to sonography findings or last menstrual period date; mother's age in 18 to 35 years; singleton; nulliparous; cephalic presentation; first trimester body mass index in range of 19.8 to 30 Kilograms per square meter. Exclusion criteria: presence of systemic diseases; abruption; postpartum bleeding; sensitivity to local anesthesia or entonox. One hundred and twenty nulliparous women were randomized in two group to take entonox (n=60) or lidocaine 2% (n=60). Intervention group received entonox two minutes before starting episiotomy incision and then entonox cut after incision, again two minutes before starting episiotomy repair until the end of the procedure to reduce the pain. Control group as routine received 5 milliliter lidocaine 2% before starting episiotomy incision and repair. The procedure of incision and repairing episiotomy was performed by one midwife. The severity of pain was measured using visual analogue scale (VAS) after repair episiotomy in two group's number each sample were recorded in a data management by another staff unaware from type of analgesia, and compared in both the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062222874N1**
Registration date: **2016-01-22, 1394/11/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Azam Honarmandpour

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Department of Research and Information Technology; Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-06-25, 1394/04/04

Expected recruitment end date

2015-09-19, 1394/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of entonox in comparison with lidocaine on severity of pain after episiotomy in nulliparous women

Public title

The effect of entonox on episiotomy pain in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

(Inclusion criteria: primi para women between 39 to 42 weeks of gestation according to sonography findings or last menstrual period date; mother’s age in 18 to 35 years; singleton; nulliparous; cephalic presentation; first trimester body mass index in range of 19.8 to 30 Kilograms per square meter. Exclusion criteria: presence of systemic diseases; abruption; post partume bleeding; sensitivity to local anesthesia or entonox).

Age

From **17 years** old to **34 years** old

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, City University, Ahvaz, Iran

City

Ahvaz

Postal code

6135715794

Approval date

2015-04-05, 1394/01/16

Ethics committee reference number

IR.AJUMS.REC.1394.151

Health conditions studied

1

Description of health condition studied

The relation ship between entonox with episiotomy pain in nulliparous women

ICD-10 code

O70.1

ICD-10 code description

Perineal laceration during delivery

Primary outcomes

1

Description

Severity of pain incision episiotomy

Timepoint

After episiotomy repair

Method of measurement

Visual Analogue Scale

2

Description

Severity of pain repair episiotomy

Timepoint

After episiotomy repair

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Side effects such as dry mouth, dizziness, increased drowsiness, nausea

Timepoint

after episiotomy repair

Method of measurement

Ask the client

Intervention groups

1

Description

Intervention group received entonox two minutes before starting episiotomy incision and then entonox cut after incision, again two minutes before starting episiotomy repair until the end of the procedure to reduce the pain. The procedure of incision and repairing episiotomy was performed by one midwife. The severity of pain was measured using visual analogue scale (VAS) after repair episiotomy number each sample were recorded in a data management by another staff. Entonox was maintained at above 10 ˚C in 24 hour before utilizing. Women in intervention group inhaled entonox deeply and slowly as they were trained. Entonox mask was putted on face by mother to inhale repeatedly according to respiration model “deep inhale pausing slow exhale rest”. Women are free to using entonox whenever they would like.

Category

Treatment - Drugs

2

Description
Control group as routine received 5 milliliter lidocaine 2% before starting episiotomy incision and again before starting episiotomy repair. The procedure of incision and repairing episiotomy was performed by one midwife. The severity of pain was measured using visual analogue scale (VAS) after repair episiotomy number each sample were recorded in a data management by another staff.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alhadi Hospital

Full name of responsible person
Azam Honarmandpour

Street address
Faculty Of Medical Sciences Shushtar ,West, Rajai Street, Shushtar, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Nahid ِJavadifar

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Ahvaz Jundishapur University of Medical Sciences, City University, Ahvaz, 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
Ahvaz 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
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Nahid Javadifar

Position
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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