

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 to assess the effects of entonox in comparison 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; abruptio; postpartum bleeding; sensitivity to local anesthesia or entonox. One hundred and twenty nulliparous women were randomized in two groups 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 groups' 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

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3622 9544

Email address

honarmandpour.a@ajums.ac.ir

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

City

Shushtar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Nahid Javadifar

Street address

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

City

Ahvaz

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

PhD, Assistant professor of Reproductive Health Research Center, Ahvaz Jundishapur University of Me

Other areas of specialty/work

Street address

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

City

Ahvaz

Postal code

6135715794

Phone

+98 61 3373 8383

Fax

Email

Nahid javadifar_341@yahoo.com

Web page address

www.ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Nahid Javadifar

Position

PhD, Assistant professor of Reproductive Health Research Center, Ahvaz Jundishapur University of Me

Other areas of specialty/work

Street address

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

City

Ahvaz

Postal code

6135715794

Phone

+98 61 3373 8383

Fax

+98 61133333477

Email

Nahid javadifa_341@yahoo.com

Web page address

www.ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Azam Honarmandpour

Position

MSc Midwifery

Other areas of specialty/work

Street address

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

City

Shushtar

Postal code

6451643541

Phone

+98 61 3622 9544

Fax

+98 61 3622 5042

Email

honarmandpour.a@gmail.com;
honarmandpour.a@ajums.ac.ir

Web page address

www.ajums.ac.ir

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