

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between Lidocaine-Prilocaine cream (EMLA) and lidocaine injection in the perineal pain relief during perineal repair in normal vaginal delivery

Protocol summary

Summary

This randomized clinical trial was done in 2011 at Shohada Tajrish hospital, Tehran, Iran. 46 primiparous women, with normal pregnancy after 37 weeks who refer for normal vaginal delivery with episiotomy, were selected and randomly assigned to either EMLA or lidocaine group. Three patients in EMLA group were excluded later because of emergency delivery or use of forceps. In EMLA group, 5 gr of cream was applied to the medio-lateral site of episiotomy one hour prior to the estimated delivery time at cervix dilatation of 9 cm and it cleaned just before delivery. No other material was used as anesthetics in this group. In addition, 5 gr of EMLA cream was used for repairing of episiotomy after delivery. In lidocaine group, 5 cc of lidocaine 2% were used for doing and later for repairing episiotomy. Demographic data, delivery characteristics, neonatal weight, repair duration, need to more anesthetics, pain during repair based on visual analog scale (VAS) and satisfaction from repair process were recorded and were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100219373N1**

Registration date: **2014-11-09, 1393/08/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-09, 1393/08/18

Registrant information

Name

Roxana Kargar

Name of organization / entity

Avicenna Research Institute

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research -Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Lidocaine-Prilocaine cream (EMLA) and lidocaine injection in the perineal pain relief during perineal repair in normal vaginal delivery

Public title

Effect of EMLA cream and lidocaine injection in pain relief during perineal repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Primipara normal vaginal delivery with gestational age more than 37; normal pregnancy; single

pregnancy; cephalic presentation Exclusion criteria: Multi-parity; sensitive to topical analgesics; need to epidural anesthesia; heart diseases; uncontrolled diabetes; neurological diseases which effect lower limb; use systemic or inhalation opium to reduce pain during labor

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences-
Medical School

Street address

Daneshjoo St., Velenjak St.

City

Tehran

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

268

Health conditions studied

1

Description of health condition studied

Pain relief during perineal repair

ICD-10 code

O74

ICD-10 code description

Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description

Pain relief during perineal repair in normal vaginal delivery

Timepoint

2 hour after delivery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Satisfaction from repair process

Timepoint

2 hours after delivery

Method of measurement

Asking patient

2

Description

Infection of episiotomy repair site

Timepoint

1 week after delivery

Method of measurement

Physical Examination

Intervention groups

1

Description

Control: 1. Using 5cc lidocaine 2% in mediolateral episiotomy site 10 minute prior to episiotomy 2. Using 5cc lidocaine 2% in mediolateral episiotomy site after delivery 3. Episiotomy repair after 10 minute

Category

Treatment - Drugs

2

Description

Intervention: 1. Using 5gr EMLA cream in mediolateral episiotomy site 1 hour prior to delivery (9cm cervix dilatation) 2. Using 5gr EMLA cream in around normal skin of episiotomy site after delivery 3. Episiotomy repair after 10 minute

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Dr. Roxnana Kargar

Street address

Tajrish Sq.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor for research -Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr. Roxana Kargar

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Daneshjoo St., Velenjak St.

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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 -Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Roxana Kargar

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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