

# 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

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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

**Street address**

Daneshjoo St., Velenjak St.

**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 -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

**Position**

Obstetrics &amp; Gynecology Specialist

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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