

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between lidocaine-prilocaine cream (EMLA) and mepivacaine infiltration for pain relief during perineal repair after childbirth in normal vaginal delivery In Vali-Asr hospital 1395

Protocol summary

Study aim

Comparison of the Effect of Lidocaine-Perilocaine Cream (XYLA Cream) and Lidocaine Injection on Reduction of Perineal Pain During Episiotomy in Natural Delivery in Vali-e-Asr Hospital, 1395

Design

Non-randomized, double-blind, controlled clinical trial

Settings and conduct

A non-specific randomized clinical trial was conducted at the maternity hospital of Valiasr Hospital, Fasa. The person who collected the data and completed the questionnaire did not know how to group the information. Also, the participants were not informed about the intervention of the other group considering that one day a type of study was done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age 37 weeks, , singleton and cephalic presentation. Exclusion criteria : sensitive to topical anesthetics or lidocaine, request epidural anesthesia, heart disease, uncontrolled diabetes, the presence of the diseases neurological involving the lower extremities and the use of opioids or method Inhalation to reduce pain during labor.

Intervention groups

In the intervention group one hour before the approximate delivery time at 9 cm dilatation in the mediolateral section, 5 g of ZYLA cream was applied to the perineum. To prevent contact with baby's head , because of sodium hydroxide, which stimulates the baby's eyes, the rest of the cream was cleaned. In this group, another anesthetics was not used to perform episiotomy. After the birth of the placenta , a 5 grams of cream was used around the healthy skin and after 10 minutes episiotomy was repaired . . In the control group, 5 cc lidocaine 2% was used before the episiotomy. Then, 5cc of lidocaine 2% was injected along the episiotomy line after placenta was born and episiotomy was

repaired.. Lidocaine 2% was used in both groups when needing more anesthesia during repair

Main outcome variables

Reducing episiotomy pain

General information

Reason for update

Acronym

pap

IRCT registration information

IRCT registration number: **IRCT20160830029608N2**

Registration date: **2018-05-22, 1397/03/01**

Registration timing: **retrospective**

Last update: **2018-05-22, 1397/03/01**

Update count: **0**

Registration date

2018-05-22, 1397/03/01

Registrant information

Name

Zahra Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 8075

Email address

moradi_z@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

2017-07-11, 1396/04/20

Actual recruitment end date

2017-11-17, 1396/08/26

Trial completion date

empty

Scientific title

Comparison between lidocaine-prilocaine cream (EMLA) and mepivacaine infiltration for pain relief during perineal repair after childbirth in normal vaginal delivery in Vali-Asr hospital 1395

Public title

Effect of XYLA ointment on episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

More than 37 weeks gestational age normal pregnancy, singleton cephalic presentation

Exclusion criteria:

hypersensitivity to topical anesthetics or lidocaine, epidural anesthesia, heart disease, diabetes, uncontrolled and neurological diseases involving lower limbs, use of systemic or inhaled opioids to reduce pain during labor

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyzer

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The outcome evaluator, the one who measured the severity of pain after episiotomy, was unaware of the type of grouping and completed the postnatal outcome questionnaire. Data analyzer does not know information of which group is being analyzed

Placebo

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Fasa University of Medical Sciences

Street address

Ebne-sina square

City

fasa

Province

Fars

Postal code

7461686688

Approval date

2016-12-27, 1395/10/07

Ethics committee reference number

IR.FUMS.REC.1395.114

Health conditions studied**1****Description of health condition studied**

Episiotomy

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes**1****Description**

Severity of pain during episiotomy

Timepoint

Immediately after episiotomy repair

Method of measurement

The Visual Analog Scale (VAS) is a vertical 10-cm linear scale, with zero indicating pain-free and 10 indicating maximum pain. Patient's satisfaction with Likert scale retrieval method is also 5 (very satisfied, dissatisfied, dissatisfied, dissatisfied, dissatisfied and completely dissatisfied)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group one hour before the approximate delivery time at 9 cm dilatation in the mediolateral section, 5 g of ZYLA cream is applied to the perineum. In this group, anesthetics will not be used to perform episiotomy

Category
Treatment - Drugs

2

Description
Control group: routine care

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Zahra Moradi
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Fasa University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Fasa University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available