Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between lidocaine-prilocaine cream (EMLA)and mepivacaine infiltration for pain relief during perinealrepair after childbirthin 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 Parainaleal 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)

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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 perinealrepair after childbirthin 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 ,epidertal anesthesia heart disease diabetes ncontrolled 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 analyser

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 squre
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 pain 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 perineumIn this group, anesthetics will not be used to perform episiotomy

Category
Treatment - Drugs

2

Description
Control group: rotine 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
Name of organization / entity
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Full name of responsible person
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Moradi_z@fums.ac.ir
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
Full name of responsible person
Zahra Moradi
Position
Faculty member
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Person responsible for updating data

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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