Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy and safety of lidocaine-prilocaine topical cream (XYLA-P) in reducing the intensity of episiotomy pain in normal vaginal delivery

Protocol summary

Study aim

The efficacy of topical lidocaine-prilocaine cream (Xyla-p) in reducing the intensity of episiotomy pain in NVD- The safety of topical lidocaine-prilocaine cream (Xyla-p) in reducing the intensity of episiotomy pain in NVD

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3 on 60 patients. Random allocation is done by cards with numbers 1 and 2.

Settings and conduct

Random allocation of two blind sides is done by cards with numbers 1 and 2. Patients and midwives are unaware of which group they are in. The intervention group receives 5cc of 2% injectable lidocaine before episiotomy and during episiotomy repair according to the standard protocol, and together with lidocaine They receive 5 grams of lidocaine-prilocaine cream by local injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Pregnant women with their first natural vaginal delivery - Age between 20 and 35 - Episiotomy incision less than 5 cm - Gestational age between 37 and 41 weeks - Informed consent Exclusion criteria : severe bleeding during delivery - the need to use a vacuum during delivery - 3rd and 4th grade perineal tear - history of sensitivity to lidocaine

Intervention groups

Before the episiotomy and during episiotomy repair, according to the standard protocol, the intervention group receives 2% lidocaine as a 5 cc injection at the site and along with local injection lidocaine, they receive lidocaine-prilocaine cream in the amount of 5 grams as a thick layer on the skin. This cream is used 30 minutes before the procedure at the episiotomy incision site. The control group received a placebo (lubricant gel) in the amount of 5 grams as a thick layer on the skin along with local injection lidocaine.

Main outcome variables

The level of pain-The level of patient satisfaction with the procedure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231025059855N1**
Registration date: **2023-12-23, 1402/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**
Update count: **0**

Registration date

2023-12-23, 1402/10/02

Registrant information

Name

Amirmohammad Aghajani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5565 8500

Email address

bshahrami@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-05-29, 1403/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy and safety of lidocaine-prilocaine topical cream (XYLA-P) in reducing the intensity of episiotomy pain in normal vaginal delivery

Public title
Topical lidocaine and pain reduction in natural childbirth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy pregnant women with first natural delivery Gestational age between 37 and 41 weeks Episiotomy incision below 5 cm Patient satisfaction

Exclusion criteria:
Heavy bleeding during childbirth The need to use a vacuum during delivery Grade 3 and 4 perineal lacerations History of previous allergy to lidocaine or prilocaine

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple, individual randomization. In this study, patients are placed in one of the study groups, including the intervention group and the control group, using the limited randomization method in the form of double-blind random allocation. Random allocation is done by cards numbered 1 and 2.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, as well as clinical caregivers and outcome evaluators in this study, were blinded to study group assignment. Participants in the intervention group receive medication and in the control group receive a placebo and do not know which group they are in. Midwives also don't know if they are using medicine or placebo. Also, the outcome evaluators who fill the questionnaire form after the procedure do not know which group the patient was in.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Baharloo Hospital , Behdari St , Rah Ahan Sq

City
Tehran

Province
Tehran

Postal code
1339973111

Approval date
2023-10-17, 1402/07/25

Ethics committee reference number
IR.TUMS.TIPS.REC.1402.091

Health conditions studied

1

Description of health condition studied
Natural Vaginal Delivery

ICD-10 code
080

ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Intensity of pain

Timepoint
After the episiotomy and 1, 2, 4 and 24 hours after the episiotomy

Method of measurement
Visual Analogue Scale

2

Description
Patient satisfaction rate

Timepoint
After the episiotomy and 1, 2, 4 and 24 hours after the episiotomy

Method of measurement
Oral questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before episiotomy and during episiotomy repair, according to the standard protocol, the intervention group receives 2% injectable lidocaine in the form of 5 cc injections and together with local injectable lidocaine, they receive 5 grams of lidocaine-prilocaine cream as a thick layer on the skin. This cream is used 30 minutes before the procedure at the episiotomy incision site.

Category
Treatment - Drugs

2

Description
Control group: The control group received injectable lidocaine and 5 grams of placebo (lubricant gel) as a thick layer on the skin.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baharloo hospital

Full name of responsible person
Zahra Ghalenoei

Street address
Baharloo Hospital , Behdari St , Rah Ahan Sq

City
Tehran

Province
Tehran

Postal code
1339973111

Phone
+98 21 5565 8500

Email
baharloo@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali Akbari Sari

Street address
Deputy Of Research And Technology, Sixth floor, The central organization of the university, Corner of Quds St, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417864513

Phone
+98 21 8163 3698

Email
vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
20

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
Tehran University of Medical Sciences

Full name of responsible person
Bita Shahrami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Dr. Shariati Research and Treatment Center, Jalal Al Ahmad St, North Kargar St

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
bshahrami@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Bita Shahrami

Position
Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Dr. Shariati Research and Treatment Center, Jalal Al Ahmad St, North Kargar St
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
bshahrami@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amirmohammad Aghajani
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
No. 54 , Sayyad Town , North Tabiat Blvd , Daryache Lake
City
Tehran
Province
Tehran
Postal code
1495847481
Phone
+98 21 4476 1899
Email
amirmohamadnew1@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
The data about the participants such as demographic information and medical history, etc is shared without mentioning their names and main characteristics. Also, the results of the study, including the main results, will be provided.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
If the individuals are approved, they can access the data and perform analysis on them by mentioning the source. Of course, they should not tamper with the data.
From where data/document is obtainable
Clinical Research Development Unit, Baharloo Hospital, Behdari St, Rah Ahan Sq 00982155658500-11 internal no. 578
What processes are involved for a request to access data/document
Submit your request through the announced communication portals. After conducting the necessary checks within one month's working time, the documents will be sent to your address.
Comments