

# 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

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#### 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

Bitra 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

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#### Province

Tehran

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#### Phone

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#### 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

Bitra Shahrami

#### Position

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**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

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**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**