

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the Effect of Lidocaine Injection with / without Epinephrine on Pain and Hemorrhage after Episiotomy in Primigravida Women

Protocol summary

Study aim

Comparison of the effect of lidocaine injection alone and lidocaine with epinephrine in reducing pain and bleeding After episiotomy

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 220 pregnant women

Settings and conduct

220 pregnant women admitted to Yas Hospital in Tehran, who are candidates for vaginal delivery, will be studied and randomly divided into two groups. In the intervention group before and after the episiotomy, lidocaine and epinephrine will be injected. The control group will receive lidocaine alone before and after the episiotomy. The group of participants and the main researcher will be unaware of the type of intervention and only the clinical caregiver will collect the data. The amount of pain is calculated by the visual analog scale (VAS) and to count the volume of bleeding, the number of completely bloody Gauze will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria include primigravida people are candidates for vaginal delivery, Age 15 years and older, single births, cephalic presentation, The anterior position of the placenta, and episiotomy indications. Exclusion criteria include drug use, history of heart disease, thyrotoxicosis, hypertension above 130.90, receiving epidural or spinal anesthesia during the labor and before delivery, history of allergy to local anesthetics

Intervention groups

In the pre- and post-episiotomy intervention group, lidocaine and epinephrine will be injected, but in the control group, lidocaine alone will be used. The amount of lidocaine injection in both groups are 2 ampoules of lidocaine hydrochloride 2% of Caspin company in a 10 cc syringe.

Main outcome variables

The amount of pain during and after episiotomy The amount of bleeding after episiotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200421047160N1**

Registration date: **2020-05-20, 1399/02/31**

Registration timing: **retrospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name

Azadeh Hosseinkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3336 2447

Email address

azihsnkhani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-29, 1395/11/10

Expected recruitment end date

2018-01-30, 1396/11/10

Actual recruitment start date

2017-03-25, 1396/01/05

Actual recruitment end date

2018-04-09, 1397/01/20

Trial completion date

2018-04-09, 1397/01/20

Scientific title

Comparison of the Effect of Lidocaine Injection with / without Epinephrine on Pain and Hemorrhage after Episiotomy in Primigravida Women	
Public title	Effect of Lidocain and Epinephrin in Episiotomy
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Primigravida with Age 15 and Older Single Birth Cephalic Presentation The anterior position of the placenta Having Episiotomy Indications Exclusion criteria: Drug use History of Heart Disease Thyrotoxicosis Blood pressure above 130/90 Receiving Epidural or Spinal Anesthesia during Labor and before delivery Sensitivity History to Local Anesthetics
Age	From 15 years old
Gender	Female
Phase	3
Groups that have been masked	• Participant • Investigator
Sample size	Target sample size: 220 Actual sample size reached: 200
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, continuous sampling and allocation of samples in the two groups studied will be simple random and individuals with entry criteria will be in one of groups A or B, which are intervention and control groups. In this way, even and odd numbers will be written on the cards separately and the cards will be randomly selected by pregnant women. If the card is odd, the sample will be in group A and if it is even, it will be in group B. This method will continue until the sample size reaches 220 people.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, two groups will be blinded: participants and the main researcher Participants will enter the study after obtaining written consent, but will be randomly assigned to the intervention or control group and will not be aware of the type of anesthetic. The main researcher will also be unaware of the type of anesthesia used and will only be aware of the cause of the birth and the clinical caregiver who is the midwife of the delivery room, and will evaluate the outcome and collect the relevant data.
Placebo	Not 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

Ansarieh St., Valiasr St., Golestan 14, No. 1055, Unit 1

City

Zanjan

Province

Zanjan

Postal code

4513622411

Approval date

2016-12-21, 1395/10/01

Ethics committee reference number

9311290013

Health conditions studied

1

Description of health condition studied

Episiotomy repair

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain during and after episiotomy

Timepoint

During episiotomy, after episiotomy, during episioraphy

Method of measurement

Visual analog scale (VAS)

2

Description

The amount of bleeding after episiotomy

Timepoint

During episiotomy, after episiotomy, during episioraphy

Method of measurement

Counting completely bloody Gauze

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: injection of lidocaine hydrochloride 2% from Caspian company in the amount of 2 ampoules of 5 mg per 100 cc with epinephrine from 1: 200,000 and 10cc syringes will be used for all injections. Two minutes after the anesthetic injection, the patient's pain will be assessed by a visual analog scale, which, if the patient complains of pain, will be re-injected at half the previous dose.

Category

Treatment - Drugs

2

Description

Control group: This group will receive only lidocaine hydrochloride 2% from Caspian Company in the amount of 2 ampoules of 5 mg in 100 cc without epinephrine and the amount of pain will be measured as the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Zahra Rezakhani

Street address

Yas Hospital Complex, next to Sarv St., North Nejat Elahi St., Karim Khan St.

City

Zanjan

Province

Zanjan

Postal code

1598718311

Phone

+98 21 4216 0166

Fax

+98 21 8894 8217

Email

yashospital@gmail.com

Web page address

<http://medicine.tums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Sahraian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Deputy of Research and Technology

City

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Postal code

1598718311

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Web page address

<http://vcr.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

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

Zanjan University of Medical Sciences

Full name of responsible person

Azadeh Hosseinkhani

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main consequences of the participants Published scientific study protocol on social networks such as researchgate A fully informed form of satisfaction

When the data will become available and for how long

3 months after the publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In case of correspondence with the responsible author

From where data/document is obtainable

Correspondence with the responsible author via email: azihsnkhani@zums.ac.ir

What processes are involved for a request to access data/document

Be a student or employee of government or university institutions

Comments