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
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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.Sahraiyan

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

City
Tehran

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Tehran

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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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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