Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of diclofenac suppository with topical lidocaine procaine ointment in controlling episiotomy site pain in primiparous women

Protocol summary

Study aim

Comparison of Diclofenac suppository with Lidocaine Procaine ointment in controlling episiotomy pain in primiparous women of Kowsar hospital

Design

Clinical trial two arm parallel groups randomised phase 3 on 120 patients. Randomized block method (balanced block randomization) was used for randomization. The size of each block is 8 and the total number of blocks is 15.

Settings and conduct

In Kowsar Hospital, for group A, Diclofenac suppository 50mg and for group B, 2.5 ٪ 2.5% topical Lidocaine-Procaine cream is used, repeated every 8 hours..If patient does not need she may not take the next dose. Pain severity is recorded immediately and 8,16,24 hours after delivery using VAS.Analgesic doses is recorded in both groups. If there is moderate to severe pain before the specified time, acetaminophen 500mg is added for patients, then need and frequency for additional analgesia use is recorded .After 24hour patients are asked about satisfaction and possible complications. Follow-up of pain intensity is done on the 3,7th day by phone

Participants/Inclusion and exclusion criteria

Inclusion;Primiparous women, age range 18-40 years, spontaneous onset of labor, singleton pregnancy, cephalic presentation of fetus ,mediolateral episiotomy in natural delivery Exclusion :postpartum hemorrhage, use of forceps and vacuum for delivery, manual removal of the placenta (corage), contraindications of NSAID, multiple rupture of the perineum

Intervention groups

In the delivery room, diclofenac 50mg suppository is used for group then repeated every eight hours according to the patient's need with a maximum dose of 150mg. In contrast, for group B, 2.5 ٪ 2.5% topical lidocaine procaine cream is used immediately then repeated every eight hour

Main outcome variables

Number and dose of Diclofenac supp or lidocaine oint use,episiotomy site pain, need and number of additional painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220129053861N1**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date

2022-02-11, 1400/11/22

Registrant information

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Fatemeh Mirzapour
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of diclofenac suppository with topical lidocaine procaine ointment in controlling episiotomy site pain in primiparous women

Public title
Comparison of Diclofenac suppository and Lidocaine ointment in controling episiotomy site pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women Age range 18-40 Spontaneous onset of labor Singleton pregnancy Cephalic presentation of fetus Mediolateral episiotomy in natural delivery
Exclusion criteria:
Postpartum hemorrhage Use of forceps and vacuum for childbirth Manual removal of placenta (placenta corage) Contraindications to Nonsteroidal Anti-inflammatory drugs Multiple perineal rupture
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Using random allocation softeware software, 120 patients are divided into A and B by balanced block randomization method. The size of each block is 8 and the total number of blocks is 15. There are 60 patients in each group. Therefore, the balanced randomization method for participants is used to study a randomized clinical trial to evaluate the effect of diclofenac suppository and lidocaine-procaine ointment in controlling episiotomy pain.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Science
Street address
Medicine faculty,Qazvin University of Medical Science,Bahonar blvd,Qazvin
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2021-09-19, 1400/06/28
Ethics committee reference number
IR.QUMS.REC.1400.266

Health conditions studied

1

Description of health condition studied
Episiotomy pain control
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sevirity of Episiotomy site pain
Timepoint
8,16,24 hour after episiotomy and then day 3 and 7 after episiotomy
Method of measurement
Visual analogue scale

2

Description
Number of Diclofenac suppository use
Timepoint
8,16,24 hour after episiotomy then day 3,7
Method of measurement
Record the frequency of use of medications received

3

Description
Number of Lidocaine Procaine Ointments use
Timepoint
8,16,24 hour after episiotomy then day 3,7
Method of measurement
Record the frequency of use of lidocaine procaine ointment

Secondary outcomes

1

Description
Frequency of use of additional analgesic
Timepoint
Before the specified time to receive the next dose of analgesia if patient needs
Method of measurement
Record frequency of additional analgesic use

2

Description
Patient satisfaction
Timepoint
Day 3,7 after episiotomy
Method of measurement
Ask patient by phone

Intervention groups

1

Description
Intervention group: Immediately after episiotomy Diclofenac suppository 50mg (Aboreyhan company)is used, then it is repeated every eight hours according to the patient's need with a maximum dose of 150 mg. If the patient does not need it and there is no pain, she can not receive the next dose and if additional painkillers are needed before the specified time,she can use Acetaminophen 500mg(shefa company)
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: For group B, immediately after delivery, 2.5 ٪ 2.5% topical Lidocaine Procaine cream (Tehranchemie company)is used and then repeated every eight hours according to the patient's needs. The drug is given to the patient 8,16,24 hours later. If the patient does not need it and there is no pain, she can not receive the next dose of the drug. If she needs analgesia before the specified time, she can use acetaminophen 500 mg(shefa company)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar hospital
Full name of responsible person
Fatemeh Mirzapour
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Mirzapour
Position

Medical Intern
Latest degree
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Other areas of specialty/work
General Practitioner
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not 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
.
When the data will become available and for how long
.
To whom data/document is available
.
Under which criteria data/document could be used
.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
.
Comments