Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of paracervical block with lidocaine on analgesia in patients undergoing colposcopy and cervical biopsy

Protocol summary

Study aim

1-Determining the effect of para-cervical block with Lidocaine on analgesia in patients undergoing colposcopy and cervical biopsy 2- Determining and comparing the mean pain during the procedure and 5 min. after the procedure in the two groups 3-Determining and comparing the average satisfaction score in the two groups

Design

Clinical trial with control group, three blinds, randomized by randomized block method; With a sample size of 74 patients, in order of admission time

Settings and conduct

This study is performed on patients referred to the outpatient clinic of obstetrics and gynecology affiliated to Shahid Sadoughi Hospital in Yazd. 30 minutes before the procedure, patients are given 100 mg diclofenac rectal suppository, then paracervical block at 3 and 9 o'clock around the cervix by injecting 10 ml of 2% lidocaine or 0.9% normal saline with syringes of the same volume and color. Which is done by another person. It is a three-blind study (patient, physician, analyzer, researcher) in which randomly blocked syringes are used for patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria:women between 18-60 years; ASA ClassI,II; Candidate for colposcopy and cervical biopsy / Exclusion criteria:patients under 18 and over 60 years; Pregnant; Drug and psychotropic addiction;Taking neuroleptic or analgesic drugs one day before the procedure; Severe systemic diseases; history of allergy to anesthetics; Dissatisfaction with the study

Intervention groups

Diclofenac rectal supp. are given to patients 30 min. before the procedure then para-cervical block is performed by injection of lidocaine or normal saline.

Main outcome variables

The amount of pain during the procedure and 5 min. after the procedure; satisfaction with the procedure; Complications (Tachy & bradycardia; hypotension;Faint;dizziness,tinnitus)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039854N1**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name
Fahimeh Nokhostin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3823 4189

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fahimeh.nokhostin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of paracervical block with lidocaine on analgesia in patients undergoing colposcopy and cervical biopsy

Public title
Evaluation of pain and satisfaction with local anesthesia in colposcopy and cervical biopsy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Females between 18-60 years old ASA Class I , II Candidate for colposcopy and cervical biopsy
Exclusion criteria:
pregnant women Drug and psychotropic addiction History of taking neurological and analgesic drugs from one day before the procedure Severe systemic diseases (cardiac dis., kidney dis., etc.) History of allergy to anesthetics Dissatisfaction with the study

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In the current study, we used block randomization method. Each block size was 2 by 2, and in total 16 blocks were considered. The acceptable sequences for packages within each block were: 1) AABB, 2) ABAB, 3) BBAA, 4) BABA, 5) ABBA, and 6) BAAB. Then each were marked from 1 to 6 as above. After that the packages within blocks were sequentially numbered from 1 to 64. Participant were consecutively numbered from 1 to 180, based on the time of admission and hospital registration code.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Two set of 74 sterile, colorless and ready to inject 10 cc syringes (2% lidocaine and normal saline for injection) were prepared and were labeled A and B before concealment. According to block randomization, each patients syringe A or B treatment. The patients, the nurses who administrated were blinded. Also, the physicians did not know which patients received the drug A or B. Hence, the patients, physicians, nurses, as well as data analyzer were blinded to the type of analgesic.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University Of Yazd

Street address
Research unit, Ali Ibn Abitaleb Medical School, Islamic Azad University Of Yazd, Shohada Gomnam boulevard, Safaeieh

City
Yazd

Province
Yazd

Postal code
8916877318

Approval date
2020-08-09, 1399/05/19

Ethics committee reference number
IR.IAU.YAZD.REC.1399.030

Health conditions studied

1

Description of health condition studied
patients undergoing colposcopy and cervical biopsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
average of pain score

Timepoint
During and 5 minutes after the procedure

Method of measurement
Pain Score (VAS 0-10)

2

Description
Satisfaction rate of the procedure

Timepoint
After the procedure

Method of measurement
Score 0-5

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diclofenac anal suppository 100, 30 minutes before the procedure and then injection of 10 cc of 2% lidocaine at 3 and 9 o'clock around the cervix
Category
Treatment - Drugs

2

Description
Control group: Diclofenac 100 anal suppository, 30 minutes before the procedure and then injection of 10 cc of normal saline 0.9% injection at 3 and 9 o'clock around the cervix
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Fahimeh Nokhostin
Street address
Office of the Department of Obstetrics and Gynecology, Shahid Sadoughi Hospital, Sahid Ghandi boulevard, Safaeieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Seyed Mohammad Reza Mortazavizadeh
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Research unit, Ali Ibn Abitaleb Medical School, Islamic Azad University Of Yazd, Shohada Gomnam boulevard, Safaeieh
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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Fahimeh Nokhostin
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
Data collection form Only part of the data that contains information about the main outcome can be shared.
When the data will become available and for how long
After official publication
To whom data/document is available
Researchers working in scientific and academic institutions
Under which criteria data/document could be used
Giving a written letter of commitment not to misuse the study data
From where data/document is obtainable
Dr. Fahimeh Nokhostin fahimeh.nokhostin@yahoo.com
What processes are involved for a request to access data/document
Proposal Confirmed letter for proposal Ethical code Related international codes
Comments