

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Determining the effectiveness of lidocaine spray in relieving pain caused by cervical biopsy through colposcopy

Protocol summary

Study aim

Determining the effectiveness of lidocaine spray in relieving pain caused by cervical biopsy through colposcopy

Design

This single-blind randomized clinical trial with parallel groups will be performed on 60 women candidates for colposcopy. Patients are randomly divided into two groups by block randomization. Prior to the biopsy, the intervention group will be received lidocaine 10% spray (4 puffs containing 10 mg per puff) over the entire length of the ectoservix, and the second group will be received placebo spray (normal saline).

Settings and conduct

This single-blind randomized clinical trial with parallel groups will be performed on 60 women candidates for colposcopy. It will be performed in a teaching hospital in Zanjan. In this study, patients, data collectors, outcome assessors, and manuscript writers will be completely unaware of the prescribing protocol.

Participants/Inclusion and exclusion criteria

Patients will be enrolled the study with abnormal cervix screening test or colposcopy findings with biopsy indication. Exclusion criteria include allergy to lidocaine , pregnancy and post-hysterectomy period.

Intervention groups

Prior to the biopsy, the intervention group will be received lidocaine 10% spray (4 puffs containing 10 mg per puff) over the entire length of the ectoservix, and the second group will be received placebo spray (normal saline).

Main outcome variables

Pain during and after biopsy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220606055087N1**

Registration date: **2022-06-12, 1401/03/22**

Registration timing: **prospective**

Last update: **2022-06-12, 1401/03/22**

Update count: **0**

Registration date

2022-06-12, 1401/03/22

Registrant information

Name

Zahra Ghomashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4252 7476

Email address

z.ghomashi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-11, 1401/05/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effectiveness of lidocaine spray in relieving pain caused by cervical biopsy through colposcopy

Public title

lidocaine spray in relieving pain caused by cervical biopsy through colposcopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with abnormal cervix screening test or colposcopy findings with biopsy indication

Exclusion criteria:

Lidocaine allergy Pregnancy Post-hysterectomy period

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method. The size of all blocks is equal. Random allocation software is also used to generate a random sequence of blocks. This software generates a random sequence in addition to generating a random sequence by blocking method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the use of two sprays with similar shapes and colors in this study, patients and individuals performing statistical analysis and those who prepare the draft of article will be completely unaware of the treatment protocol.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhori BLV.

Azadi Squ. Zanjan

City

Zanjan

Province

Zanjan

Postal code

1435689752

Approval date

2022-06-05, 1401/03/15

Ethics committee reference number

IR.ZUMS.REC.1401.071

Health conditions studied

1

Description of health condition studied

Pain after biopsy

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain after biopsy

Timepoint

Immediately after biopsy and 10 minutes after biopsy

Method of measurement

The Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In lithotomy position, after inserting a speculum, 4 puff of 10% concentration of lidocaine spray (each puff contains 10 mg of lidocaine) is sprayed in the vaginal area and cervix.

Category

Treatment - Drugs

2

Description

Control group: 4 puffs of normal saline spray

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Zahra Ghomashi

Street address

Ayatollah Mousavi Hospital, Gavazang Road, Zanjan

City

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1425678922

Phone

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Email

Z.ghomashi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

Street address

Zanjan University of Medical Sciences Campus, Dr.
Yousef Sabouti Blvd., Zanjan

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4513956184

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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

Zanjan 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

Zahra Ghomashi

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Zahra Ghomashi

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Zahra Ghomashi

Position

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Latest degree

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data including the main and secondary outcomes can be shared.

When the data will become available and for how long

Access period starts from 2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable

To receive the required documents or data, contact the Responsible person of the project (Dr. Zahra Ghomashi) by email: Z.ghomashi@yahoo.com.

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

To receive the required documents or data, contact the Responsible person of the project (Dr. Zahra Ghomashi) by email: Z.ghomashi@yahoo.com and send a written and signed request to her.

Comments