

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of The Effect of 10% Lidocaine Spray on Reducing the Pain of IUD Insertion

Protocol summary

Summary

Intrauterine device (IUD) is one of the most efficient contraceptive methods. but, IUD insertion is accompanied by pain and discomfort. This study evaluated the analgesic effects of 10% Lidocaine spray in reducing IUD insertion pain. In a randomized clinical trial, 80 volunteers for IUD insertion were selected from women who refer to Urmia Nikkiah Urban Health Center and randomly allocated to two groups. The intervention group received four puffs of 10% Lidocaine spray (40 mg) on their cervix prior to IUD insertion. The routine procedure (without an analgesic) was followed in the control group. Then IUD insertion was done in Litatomy position by ministry of health guideline. The intensity of perceived pain in both groups was measured using a visual analog scale 0 to 10 Cm and the data was analyzed by statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042333608N1**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Maryam Hajiesmaello

Name of organization / entity

Urmia Branch, Islamic Azad University

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Recruitment status

Recruitment complete

Funding source

Urmia Branch, Islamic Azad University

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Effect of 10% Lidocaine Spray on Reducing the Pain of IUD Insertion

Public title

Evaluation of The Effect of 10% Lidocaine Spray on Reducing the Pain of IUD Insertion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: No allergies to Lidocaine; Haven't received analgesics and narcotics during the 24 hours before IUD insertion; History of childbirth up to 3 times; no any contraindication for IUD insertion (suspected pregnancy; history of pelvic inflammatory disease; abnormal uterine anatomy; Wilson's disease; unexplained vaginal bleeding and cervical malignancy)
Exclusion Criteria: Problem to IUD insertion; uterine size smaller than 6 cm or larger than 9 cm.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Vice Chancellor for Health of Urmia University of Medical Sciences

Street address

Vice Chancellor for Health of Urmia University of Medical Sciences, Orjans Town, Resalat Blv, Urmia, Iran

City

Urmia

Postal code

5714783734

Approval date

2014-02-24, 1392/12/05

Ethics committee reference number

P/05124284/92

Health conditions studied**1****Description of health condition studied**

The Effect of 10% Lidocaine Spray on Reducing the Pain of IUD Insertion

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Pain

Timepoint

Pain at baseline and during and after IUD insertion.

Method of measurement

Visual Scale Analog

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group received local anesthetic by four puffs of 10% lidocaine (40 mg) at cervical area three minutes prior to IUD insertion

Category

Prevention

2**Description**

The control group (routine IUD insertion without analgesia)

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Urmia Nikkhah Urban Health Center

Full name of responsible person

Poone Ebne AbdolAli

Street address

Urmia Nikkhah Urban Health Center, Near West Terminal, Dokhaniaat Junc, Urmia, Iran

City

Urmia

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor For Research Of Urmia Branch, Islamic Azad University

Full name of responsible person

Nazanin Shafiee

Street address

Urmia Branch, Islamic Azad University, 2th Kilometer of Airport road, Urmia, Iran

City

Urmia

Grant name
Grant code / Reference number
1039508050035
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor For Research Of Urmia Branch, Islamic Azad University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty