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 reefer to Urmia Nikkhah 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, Dokhaniat 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
Urmia Branch, Islamic Azad University

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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