Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of three methods of using topical lidocaine gel into cervix, intrauterine infusion of lidocaine and combination of them on reducing the pain during curettage.

Protocol summary

Summary

Objectives: this study compares the efficacy of the intracervical application of lidocaine gel, the intrauterine infusion of lidocaine, and the co-administration of these procedures in alleviating pain during curettage. Design: it was a unicentric, randomized, and unblinded study. Population: pregnant women (n=120) with a dilated cervix, in the 8th-13th week of pregnancy and hospitalized in Kowsar Hospital in Qazvin participated in the study. Inclusion and exclusion criteria: being in the 8th-13th week of pregnancy and having a dilated cervix were the inclusion criteria. Using an analgesic 24 hours before curettage and having genital infections, severe uterine bleeding, drug addiction, and a history of allergy to lidocaine were set as the exclusion criteria. Setting: the subjects were assigned to three groups. Group 1 received an intrauterine lidocaine infusion and intracervical lidocaine gel. An intrauterine lidocaine infusion and placebo gel were administered to the second group. Group 3 received intracervical lidocaine gel and an intrauterine infusion of normal saline. Interventions: in the first group, 5 cc of 2% lidocaine was intrauterinally infused and 3 cc of the lidocaine gel was applied over the cervix. In the second group, 5 cc of 2% lidocaine was intrauterinally infused and 3 cc of the placebo gel was applied over the cervix. In the third group, 5 cc of normal saline was intrauterinally infused and 3 cc of the lidocaine gel was applied over the cervix. Primary outcome variables: exploring the effectiveness of local analgesia during curettage and obviating the need for general anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707139576N3**

Registration date: **2017-10-22, 1396/07/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name

Ezzatsadat Haji seyed javadi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3223 6374

Email address

ehajiseyedjavadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Qazvin University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of three methods of using

topical lidocaine gel into cervix, intrauterine infusion of lidocaine and combination of them on reducing the pain during curettage.

Public title
Comparison of the effect of three methods of using localized analgesia on reducing the pain during curettage.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: being in the 8th-13th week of pregnancy and having a dilated cervix. Exclusion criteria: having a genital infection; suffering from severe uterine bleeding; being a drug addict; having a history of allergy to lidocaine and taking an analgesic 24 hours before curettage.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
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 Sciences
Street address
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Postal code
Approval date
2017-05-13, 1396/02/23
Ethics committee reference number
IR.QUMS.REC.1396.83

Health conditions studied

1

Description of health condition studied
Local anasthetics
ICD-10 code
Y48.3
ICD-10 code description
Local anaesthetics

Primary outcomes

1

Description
Localized analgesia
Timepoint
During localized analgesia, during curettage, 15, 30 and 60 minutes after curettage
Method of measurement
Vas pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Itervention3: intrauterine Infusion of 5 cc normal saline and 3cc lidocain gel.
Category
Treatment - Drugs

2

Description
Intervention1: intrauterine Infusion of 5 cc lidocain 2% and 3cc lidocain gel.
Category
Treatment - Drugs

3

Description
Intervention 2: intrauterine Infusion of 5 cc lidocain 2% and 3cc placebo gel.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Ayda Zeinali

Street address
Kowsar Hospital, Taleghani St, Qazvin, Iran
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research of Qazvin University of Medical Sciences
Full name of responsible person
Dr Amir Peymani
Street address
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research of Qazvin University of Medical Sciences
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
Kowsar Hospital
Full name of responsible person
Ayda Zeinali
Position
Resident
Other areas of specialty/work
Street address
Kowsar Hospital, Taleghani St, Qazvin, Iran
City
Qazvin
Postal code
Phone
+98 28 3223 6374
Fax
Email
aydazeinali@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kowsar Hospital
Full name of responsible person
Ezzat Alsadat Hajiseyedjavadi
Position
Asistant Professor, Department of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Kowsar Hospital, Taleghani St, Qazvin, Iran
City
Qazvin
Postal code
Phone
+98 910 957 3745
Fax
Email
aydazeinali@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kowsar Hospital
Full name of responsible person
Ayda Zeinali
Position
Resident
Other areas of specialty/work
Street address
Kowsar Hospital, Taleghani St, Qazvin, Iran
City
Qazvin
Postal code
Phone
+98 28 3223 6374
Fax
Email
Web page address

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