Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of lidocaine gel on pain from copper IUD insertion: A randomized controlled trial

Protocol summary

Summary
The aim of this randomized controlled trial is to determine the effect of lidocaine 2% gel on pain from copper IUD insertion. It will be took place in Bavafa health center in Tabriz, a center with about 70 IUD insertion a month. In group 1, lidocaine 2% gel and in group 2, lubricant gel will be placed in the cervical canal by a sterile swab one minute before IUD insertion and the group 3 will get no intervention. Immediately after IUD insertion, pain score will be assessed by the investigator using 10 cm visual scale.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138903093706N3**
Registration date: **2010-09-21, 1389/06/30**
Registration timing: **prospective**

Last update:
Update count: **0**
Registration date
2010-09-21, 1389/06/30

Registrant information
Name
Sakineh Mohammad-Alizadeh-Charandabi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3477 2699
Email address
alizades@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source
Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date
2010-09-23, 1389/07/01
Expected recruitment end date
2010-12-21, 1389/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of lidocaine gel on pain from copper IUD insertion: A randomized controlled trial

Public title
Effect of lidocaine gel on pain from copper IUD insertion: A randomized controlled trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: All IUD clients of Bavafa health center who have no IUD contraindication, including: Pregnancy, puerprium sepsis, pelvic inflammatory disease or sexually transmitted infections (currently or in past 3 months), known or suspected uterine or cervical cancer, unknown genital abnormal bleeding, uterine fibroids and tumors causing deformity in uterus. Exclusion criteria: any problem during IUD insertion for any reason; in this case another gel with the same number will be replaced.
Age
From **15 years** old to **48 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size

Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research deputy of Tabriz university of medical sciences

Street address
Golgasht St.

City
Tabriz

Postal code
118-51665

Approval date
empty

Ethics committee reference number
8918

Health conditions studied

1

Description of health condition studied
pain from copper IUD insertion

ICD-10 code
Z30.1

ICD-10 code description
Insertion of (intrauterine) contraceptive device

Primary outcomes

1

Description
pain severity

Timepoint
Immediately after IUD insertion

Method of measurement
10 cm visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Group 3 will get no intervention.

Category
N/A

2

Description
Group 1: lidocaine 2% gel will be placed in the cervical canal by a sterile swab one minute before IUD insertion

Category
Prevention

3

Description
Group 2: lubricant gel will be placed in the cervical canal by a sterile swab one minute before IUD insertion.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Bavafa health center

Full name of responsible person
Farideh Kazemi

Street address
Monajjem blvd

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy of Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad-Reza Rashidi

Street address
Golgasht St.

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Deputy of Tabriz 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
Tabriz university of medical sciences
Full name of responsible person
Farideh Kazemi
Position
Midwifery graduate student
Other areas of specialty/work
Street address
Golgasht St.
City
Tabriz
Postal code
Phone
+98 81 1254 9670
Fax
Email
f.kazemi21@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences, Faculty of Nursing and Midwifery
Full name of responsible person
Sakineh Mohammad-Alizadeh Charandabi
Position
Assistant professor, PhD in Reproductive Health
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery, South Shariati
City
Tabriz
Postal code
Phone
+98 41 1477 2699
Fax
+98 41 1479 6969
Email
alizades@tbzmed.ac.ir , smoalch@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz university of medical sciences
Full name of responsible person
Farideh Kazemi
Position
Midwifery graduate student
Other areas of specialty/work
Street address
Golgasht St.
City
Tabriz
Postal code
Phone
+98 81 1254 9670
Fax
Email
f.kazemi21@gmail.com
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