Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison of EMLA cream and placebo on pain during IUD insertion in women referred to health centers of Imam Hussein.

Protocol summary

Summary

The purpose of this study is to determine the effect of EMLA cream on pain of intrauterine device insertion. It is a randomized clinical trial study. Candidate women for intrauterine device insertion (n=100), who had eligible criteria(Including: age between 20 to 35 years without contraindication IUD insertion, to between 2 and 5 days of menstruation), were recruited in this study and randomized into two groups: (1) EMLA cream (n=50), (2) placebo group (n=50).In both groups, 5 g cream be used after insertion of a speculum on the cervix area. Data were collected by demographic questionnaire and pain visual analogue scale.Pain in the fifth round after speculum insertion, after applying Tenaculum، removal Hysterometer and after IUD inserion and extubation insertion tube was measured. Average pain induced by IUD insertion was compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209015698N4**
Registration date: **2012-10-05, 1391/07/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-05, 1391/07/14

Registrant information

Name

Mahbobeh Ahmadi

Name of organization / entity

Shahid Beheshti University of Medical & Health Service

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of EMLA cream and placebo on pain during IUD insertion in women referred to health centers of Imam Hussein.

Public title

Effect of EMLA cream on pain during insertion of IUD

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Women aged 35-20 year؛ Visit during menstruation (days 5-1 cycles)؛ Do not use pain medication (acetaminophen, ibuprofen, mefenamic acid) 6 hours before visiting؛ No contraindication for IUD insertion exclusion criteria: Sensitivity EMLA cream (Genesis symptoms of itching, burning, swelling in the area of the cervix)؛ uterine size less than 6 cm and 9 cm؛ Cervical stenosis

Age

From **20 years** old to **35 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Shahid Beheshti University of Medical Sciences
Street address
next to Ayatollah Taleghani Hospital, Evin, Shahid Chamran Highway,Tehran.
City
Tehran
Postal code
Approval date
2012-07-08, 1391/04/18
Ethics committee reference number
400/3383

Health conditions studied

1

Description of health condition studied
Pain of iud insertion
ICD-10 code
Z30.1
ICD-10 code description
Presence of (intrauterine) contraceptive device

Primary outcomes

1

Description
pain IUD insertion
Timepoint
after application of Speculum, tenaculum, hysterometer, insertion IUD and instrument removal
Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
In the first group, seven minutes before insertion of the IUD, 5 g EMLA cream placed on the cervix area with swab cotten.
Category
Treatment - Drugs

2

Description
In the second group, seven minutes before insertion of the IUD 5 g placebo cream placed on the cervix area with swab cotten.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein Medical Center
Full name of responsible person
Ms. Biglari
Street address
Imam Hussein Medical Center, Khezr, Hamedan.
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Doctor Masoume Simbar
Street address
School of Nursing and Midwifery, Niayesh blvd Valiasr st cross, Tehran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Shahid Beheshti 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

Fatemiye Hospital.

Full name of responsible person

Samira Tavakolian

Position

Midwifery Graduate Student

Other areas of specialty/work

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Master of Midwifery

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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