

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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 sizeTarget 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, hystrometer,

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 cotton.

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 cotton.

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, Kheyr, 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
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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