

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7747 5651

###### Email address

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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, 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**  
Fatemiye Hospital.  
**Full name of responsible person**  
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## Person responsible for scientific inquiries

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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*