# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of chammomile essential oil on pain intensity of IUD insertion

## Protocol summary

**Summary**

Background and aim: Intrauterine device (IUD) is a safe, effective and reversible method; however IUD insertion is associated with pain. The purpose of this study was to determine the effect of chammomile essential oil on pain of intrauterine device insertion. Materials and Methods: It was a randomized clinical trial study. Candidate women for intrauterine device insertion (n=150), who had eligible criteria, were recruited in this study and randomized into three groups: (1) chammomile group (n=50), (2) placebo group (n=50) and (3) control group (n=50). Data were collected by demographic questionnaire and pain visual analogue scale. Average pain induced by IUD insertion was compared between groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201202078950N1**
Registration date: **2012-03-01, 1390/12/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-03-01, 1390/12/11

**Registrant information**

**Name**

Mina Kashiha

**Name of organization / entity**

Nursing and Midwifery school, Shahid Beheshti University of Medical Sciences

**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**

2010-10-23, 1389/08/01

**Expected recruitment end date**

2011-03-03, 1389/12/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of chammomile essential oil on pain intensity of IUD insertion

**Public title**

The effect of chammomile essential oil on pain of IUD insertion

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: ages between 18-48 years; Iranian race; speaking in Farsi; can read & write; no cold or smelling disorder; no usage of alleviating during last 24 hours; no smoking or opiate; no asthma. Exclusion criteria: allergy to chammomil; misusages of chammomil.

**Age**

From **18 years** old to **48 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single 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**

Niayesh blvd., Valiasr st. cross

**City**

Tehran

**Postal code**

**Approval date**

2011-01-09, 1389/10/19

**Ethics committee reference number**

1-7282-86-01-89

## Health conditions studied

### 1

**Description of health condition studied**

pain in IUD insertion

**ICD-10 code**

Z97.5

**ICD-10 code description**

Presence of (intrauterine) contraceptive device

## Primary outcomes

### 1

**Description**

pain

**Timepoint**

immediately after IUD insertion

**Method of measurement**

pain ruler

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Second group: placebo (propylene glycol) usage in the same manner as first group.

**Category**

Placebo

### 2

**Description**

Third group use nothing.

**Category**

N/A

### 3

**Description**

First group: aromatherapy with chammomil essensial oil. We use 3 drops of chammomil essensial oil on a cotton and put it in the caped dark glass. Before IUD insertion they should inhale it for 5 minutes from a distance of 7-10 cm from their nose.

**Category**

Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shohadaye Fardis health services

**Full name of responsible person**

Mrs Sadidy

**Street address**

Kanale-ab avenue

**City**

Karaj

### 2

**Recruitment center**

**Name of recruitment center**

Shohadaye Aghtape health services

**Full name of responsible person**

Mrs Pakdaman

**Street address**

west street, Valiasr blvd, Aghtape

**City**

Karaj

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nahid Khodakarami
**Street address**
Taleghani hospital
**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**
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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*