

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of chamomile 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 chamomile 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) chamomile 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

+98 912 483 0396

###### Email address

pr\_shohada@sbmu.ac.ir

##### 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 chamomile essential oil on pain intensity of IUD insertion

##### Public title

The effect of chamomile 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 chamomil; misusages of chamomil.

##### 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 essential oil. We use 3 drops of chammomil essential oil on a cotton and put it in the capped 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**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mina Kashiha

**Position**

master of science

**Other areas of specialty/work**

**Street address**

Shohada hospital

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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master of midwifery

**Other areas of specialty/work**

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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*