

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 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

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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