Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effec of inhaler Lavender on Anexity and pain of copper intra uterin device insertion

Protocol summary

Summary
The aim of this randomized controlled trial is to determin the effect of aromatherapy on anexity and pain of copper IUD insertion .This study will be done in bahonar health center in Ardebil city . After taking written consent of recruited samples ,demoghraphic and Spiel Berger questionaire will be filled up,and Palse and Blood Pressure will be mesured by investigator .in group1(intervention),lavender and in group 2(control),placebo will be inhalated for 30 minute before IUD insertion.At the time of insertion IUD Spiel Berger questionaire will be filled up,and Palse and Blood Pressure will be mesured.Immediatly after IUD insertion,pain score will be assessed using 10 cm visual analog scale.

General information

Acronym
Prevention
IRCT registration information
IRCT registration number: **IRCT201107076709N2**
Registration date: **2011-11-12, 1390/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2011-11-12, 1390/08/21

Registrant information
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Recruitment status
Recruitment complete
Funding source
Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date
2011-09-23, 1390/07/01
Expected recruitment end date
2012-01-20, 1390/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effec of inhaler Lavender on Anexity and pain of copper intra uterin device insertion

Public title
Effect of Aromatherapy on anexity and pain of copper intra uterin device insertion :A Randomised controlled trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclution criteria: All IUD clients of bahonar health center of Ardebil city who have no IUD contraindication including:Pregnancy;puerperium sepsis;pelvic inflametory disease or sexually trasmitted infections(currently or in past 3 months);uterin or cervical cancer;unknown genital bleeding;uterin abnormality and fibroid tumors causing deformity in uterus.exclusion criteria:any alergy during Aromatherapy.
Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research deputy of Tabriz university of medical sciences
Street address
Golgasht St.
City
Tabriz
Postal code
51665-118
Approval date
2011-09-15, 1390/06/24
Ethics committee reference number
4685/4/5

Health conditions studied

1

Description of health condition studied
Anexity and pain from copper IUD insertion
ICD-10 code
Z30.1
ICD-10 code description
Insertion of (intrauterine) contraceptive device

Primary outcomes

1

Description
Anexity of IUD insertion
Timepoint
Before and time of IUD insertion
Method of measurement
Spiel Berger Quationaire

Secondary outcomes

1

Description
pain of IUD insertion
Timepoint
Immediately after IUD insertion
Method of measurement
10 cm Visual Analog Scale

Intervention groups

1

Description
Group 1(Intervention):A piece of cotton contain 3 drops of inhaler lavender will be inhalated normaly by the client during 30 minute before IUD insertion
Category
Prevention

2

Description
Group 2(Control):A piece of cotton contain 3 drops of placebo will be inhalated normaly by the client during 30 minute before IUD insertion
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Health Center
Full name of responsible person
Roya Nikjoo
Street address
Samanabad-Vahdat square
City
Ardebil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Golgashat Street

City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Tabriz 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

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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