Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of short-term complications (mensturation patern), satisfaction and quality of life in Mirena users as a contraception method with Copper IUD users

Protocol summary

Summary

Background: Complications of IUDs are the main reasons why women discontinue this effective contraception method. There are possible differences in the complications of copper and Levonorgetrol-releasing IUDs Mirena that affect which IUD to select. This study is designed to compare the short-term complications, satisfaction and quality of life of these two types of IUDs. Methods: This double-blinded clinical trial will be done on 160 women of 20-35 years old referring to Ayat Health Center for IUD contraception. By block randomization, cases will be divided into two groups: Levonorgetrol IUD, 80 individuals in group A (Mirena, Shering Company, Germany) and 80 invdividuals in Copper 380-A IUD, group B (India). In the initial visit and 1, 3 and 6 months follow-ups, short-term complications will be assessed by a gynecologist.Quality of life and satisfaction will be assessed by sf36 questionnaire and asking 3 questions respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903013881N2**
Registration date: **2011-10-21, 1390/07/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-21, 1390/07/29

Registrant information

Name
Toktam Tavakolianfar
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2004-12-31, 1383/10/11

Expected recruitment end date

2005-12-31, 1384/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of short-term complications (mensturation patern), satisfaction and quality of life in Mirena users as a contraception method with Copper IUD users

Public title

Contraception method IUD,copper IUD and mirena

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age20-35; normal menstruation; multi-parity and a negative pop smear result in the previous six months. Exclusion criteria: pregnancy; abnormal menstruation (irregularity, oligomenorrhea, hypermenorrhea and menorrhagia); malignancies of

uterine; ovaries and breasts; a personal and familial history of mass in breasts; uterine anomaly or myoma; pelvic inflammatory disease; psychiatric disorders; Body mass index more than 32; multi-partnership of the individual or her spouse; chronic systemic diseases including renal failure; hepatic cirrhosis; and cardiovascular diseases; consumption of drugs related to the cardiovascular diseases

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: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research of Tehran University of Medical Sciences

Street address
Ghods st, Keshavarz blvd

City
Tehran

Postal code
14194

Approval date
2004-03-07, 1382/12/17

Ethics committee reference number
1539/ 2004

Health conditions studied

1

Description of health condition studied
Sequelae of complication of pregnancy, childbirth and the puerperium

ICD-10 code
O98

ICD-10 code description
Sequelae of complication of pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
dysmenorrehea

Timepoint
frist visit and 1,3,6 months after IUD insertion

Method of measurement
questionnare

2

Description
quality of life

Timepoint
first visit before IUD insertion and 6 months after iud insertion

Method of measurement
questionnare

Secondary outcomes

1

Description
menorrhagia

Timepoint
1,3,6 month after iud insertion

Method of measurement
questionnare

2

Description
headache

Timepoint
1,3,6 month after iud insertion

Method of measurement
questionnare

3

Description
backpain

Timepoint
1,3,6 month after iud insertion

Method of measurement
questionnare

4

Description
breast tenderness

Timepoint
1,3,6 months after iud insertion

Method of measurement

questionnare

5

Description
spoting
Timepoint
1,3,6 months after iud insertion
Method of measurement
questionnare

6

Description
discharge
Timepoint
1,3,6 months after iud insertion
Method of measurement
questionnare

7

Description
stisfaction
Timepoint
6 months after iud insertion
Method of measurement
questionnare

8

Description
ackne
Timepoint
1,3,6 months after iud insertion
Method of measurement
questionnare

9

Description
weight gain
Timepoint
1,3,6 months after iud insertion
Method of measurement
questionnare

Intervention groups

1

Description
copper IUD
Category
Prevention

2

Description
mirena IUD
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Ayat center
Full name of responsible person
Toktm Tavakolianfar
Street address
Islamic azad university Neyshabur branch
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Neyshabur

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Ramezanzadeh
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Keshavarz blvd
City
Tehran
Grant name
1539/ 2004
Grant code / Reference number
3000000
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tehran 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