

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of short-term complications (menstruation pattern), 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 Levonorgestrel-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: Levonorgestrel IUD, 80 individuals in group A (Mirena, Shering Company, Germany) and 80 individuals 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

Name of organization / entity

Islamic Azad University, Neyshabur Branch

Country

Iran (Islamic Republic of)

Phone

+98 55 1662 1905

Email address

tavakolianfar@iau-neyshabur.ac.ir

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 (menstruation pattern), 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: age 20-35; normal menstruation; multiparity 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**

dysmenorrhea

Timepoint

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

Method of measurement

questionnaire

2**Description**

quality of life

Timepoint

first visit before IUD insertion and 6 months after iud insertion

Method of measurement

questionnaire

Secondary outcomes**1****Description**

menorrhagia

Timepoint

1,3,6 month after iud insertion

Method of measurement

questionnaire

2**Description**

headache

Timepoint

1,3,6 month after iud insertion

Method of measurement

questionnaire

3**Description**

backpain

Timepoint

1,3,6 month after iud insertion

Method of measurement

questionnaire

4**Description**

breast tenderness

Timepoint

1,3,6 months after iud insertion

Method of measurement

questionnaire

5

Description

spoting

Timepoint

1,3,6 months after iud insertion

Method of measurement

questionnaire

6

Description

discharge

Timepoint

1,3,6 months after iud insertion

Method of measurement

questionnaire

7

Description

stisfaction

Timepoint

6 months after iud insertion

Method of measurement

questionnaire

8

Description

ackne

Timepoint

1,3,6 months after iud insertion

Method of measurement

questionnaire

9

Description

weight gain

Timepoint

1,3,6 months after iud insertion

Method of measurement

questionnaire

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

City

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

Street address

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

Contact

Name of organization / entity

Islamic Azad University, Neyshabur Branch

Full name of responsible person

Toktam Tavakolianfar

Position

Msc, member of faculty

Other areas of specialty/work

Street address

Department of Midwifery, Neyshabur Branch, Islamic

Azad university

City

Neyshabur

Postal code

9319613668

Phone

+98 55 1662 1904

Fax

+98 55 1661 5472

Email

tavakolianfar@iau-neyshabur

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Neyshabur Branch

Full name of responsible person

Toktam Tavakolianfar

Position

Msc, member of faculty

Other areas of specialty/work

Street address

Department of Midwifery, Neyshabur Branch, Islamic Azad university

City

Neyshabur

Postal code

00985519319613668

Phone

+98 55 1662 1904

Fax

+98 55 1661 5472

Email

tavakolianfar@iau-neyshabur.ac.ir

Web page address

www.iau-neyshabur.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Toktam Tavakolianfar

Position

Msc, member of faculty

Other areas of specialty/work

Street address

Department of Midwifery, Neyshabur Branch, Islamic Azad university

City

Neyshabur

Postal code

9319613668

Phone

+98 55 1662 1904

Fax

+98 55 1661 5472

Email

tavakolianfar@iau-neyshabur.ac.ir

Web page address

www.iau-neyshabur.ac.ir

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