

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Surgical versus medical treatment for abnormal uterine bleeding in premenopausal women

Protocol summary

Summary

The aim of this study is to investigate the effects of Surgical versus medical treatment for abnormal uterine bleeding in premenopausal women. In this randomized clinical trial, 97 women premenopausal women, aged 40-55 years, with complaint of abnormal uterine bleeding were recruited. After obtaining informed consent, ultrasonography and endometrial biopsy or D&C were performed and atypical hyperplasia, uterine malignancy or organic disorders were ruled out. Then, the patients were randomly allocated to undergo abdominal hysterectomy or receiving diphereline, 3.75 mg IM every 28 days for 3 doses. All the patients were interviewed before intervention, 3 months, 6 months and 2 years after the interventions and improvement of uterine bleeding as early outcome and anemia and quality of life as secondary outcomes were evaluated and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103065563N3**

Registration date: **2011-03-24, 1390/01/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-03-24, 1390/01/04

Registrant information

Name

Elaheh Ouladsahebmadarek

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1554 1221

Email address

madarek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2007-05-13, 1386/02/23

Expected recruitment end date

2010-03-14, 1388/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surgical versus medical treatment for abnormal uterine bleeding in premenopausal women

Public title

Surgical versus medical treatment for abnormal uterine bleeding in premenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Premenopausal women between 40-55 years old with abnormal uterine bleeding for at least 2 months which is described as bleeding more than 7 days in a month or heavy bleeding resulting in anemia (Hct<32%), no evidence for atypical hyperplasia or carcinoma in D&C, no response to simple medications such as medroxy progestone and contraceptive tablets, no Ovarian or uterine organic lesions (ruled out by using clinical examination and ultrasonography) Exclusion

criteria: Anemia for other reasons, Fertility preservation, Evidence of pregnancy, Endocrinopathy, Coagulopathy, contraindications for medical treatment, Using IUD

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **97**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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, Tabriz University of Medical Sciences

Street address

Golgasht Ave.

City

Tabriz

Postal code

Approval date

2006-11-02, 1385/08/11

Ethics committee reference number

6376/4/5

Health conditions studied

1

Description of health condition studied

Abnormal uterine bleeding

ICD-10 code

N93.8

ICD-10 code description

Other specified abnormal uterine and vaginal bleeding

Primary outcomes

1

Description

Uterine bleeding

Timepoint

before intervention, 2, 3 months and 2 years after intervention

Method of measurement

asking from patient

Secondary outcomes

1

Description

anemia

Timepoint

before intervention, 2, 3 months and 2 years after intervention

Method of measurement

Hb and Hct analysis

2

Description

quality of life

Timepoint

before intervention, 2, 3 months and 2 years after intervention

Method of measurement

WHOOQL standard questionnaire

Intervention groups

1

Description

diphereline 3.75 mg IM every 28 days for 3 doses

Category

Treatment - Drugs

2

Description

standard surgical treatment (abdominal hysterectomy)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Elaheh ouladsahebmadarek

Street address

South Artesh Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi

Street address

Golgasht Ave.

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, 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

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Full name of responsible person

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address**

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