Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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 concept, 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 he 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

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Elaheh Ouladsahebmadarek
Name of organization / entity
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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 heperplasia or carcinoma in D&C, no response to simple medications such as medroxy progetrone 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 questionaire

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

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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