

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of two kinds of treatment with thermal balloon and hysteroscopy in the treatment of abnormal uterine bleeding

Protocol summary

Summary

Menorrhagia is one of the most common reasons for referral to gynecologists. Many women do not respond to medical treatment and are candidate for hysterectomy. Some of them who are in their middle age don't like to have hysterectomy and those who are older are not candidate for medical treatment and surgical hysterectomy due to internal diseases in this age. So, endometrial ablation is one of suggested treatments. This clinical trial will be done on women with menorrhagia who have not responded to medical treatment. Patients are categorized into two groups: endometrial ablation with thermal balloon (intervention group, 35 patients) and endometrial ablation with hysteroscopy (control group, 25 patients). Information such as age, parity, BMI, dysmenorrhea, menstrual period, duration of menorrhagia, treatment taken, medical history, underlying disease, history of previous surgery will be recorded. Postoperative complications of hysteroscopy including bleeding, infection, uterine perforation, thermal injury, and complications after thermal balloon including thermal injury to the bowel, bleeding, uterine perforation, adenexal necrosis are recorded. All patients are followed for one year. Outcomes for each patient will be recorded for 6 months and 12 months after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207163820N5**

Registration date: **2012-08-18, 1391/05/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-18, 1391/05/28

Registrant information

Name

Zinatalsadat Bouzari

Name of organization / entity

Babol university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 4651

Email address

z_b412003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Babol University of Medical Sciences

Expected recruitment start date

2011-11-09, 1390/08/18

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two kinds of treatment with thermal balloon and hysteroscopy in the treatment of abnormal uterine bleeding

Public title

Treatment of abnormal uterine bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1 - no response to treatment; 2 - lack

of desire for fertility and having children; 3 - normal cervical cytology; 4 - normal endometrial histology. Exclusion criteria: 1 - intrauterine pathologies (such as polyps or submucosal fibroma); 2 - Uterine cavity length more than 12 cm; 3 - hyperplasia or endometrial atyp.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Not 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 and technology, Babol University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafoz Avenue

City

Babol

Postal code**Approval date**

2012-07-01, 1391/04/11

Ethics committee reference number

6646

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**

The amount of vaginal bleeding

Timepoint

6 month and 12 month

Method of measurement

Visual Analogue Scale

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

Perforation of the uterus after treatment

Timepoint

Intraoperative

Method of measurement

Clinical

2**Description**

Uterine infection after treatment

Timepoint

7-3 days after intervention

Method of measurement

Clinical

Intervention groups**1****Description**

Frist group:treatment with tharmal balloon, Intervention group

Category

Treatment - Surgery

2**Description**

Second group:treatment with hysteroscop, control group

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatolah Rohani Hospital

Full name of responsible person

Dr. Zinatossadat Bouzari

Street address

Rohani Hospital

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and technology, Babol
University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences, Gangafroz Avenue

City

Babol

Grant name

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Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and technology, Babol
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

Babol University of Medical Sciences

Full name of responsible person

DR. Zinatossadat Bouzari

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific

inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Fatemehzahra Fertility & reproductive Health
Research Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/Responsible for Public Affairs Research Center

Other areas of specialty/work

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Fatemehzahra Fertility & reproductive Health
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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