

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Assessment the Effect of Myrtus Communis L. (Myrtle) fruit syrup (B 438 syrup) in hypermenorrhea

#### Protocol summary

##### Summary

This study aimed to determine the effect of Myrtle fruit syrup on the excessive uterine bleeding. This study is a randomized double blind clinical trial with negative control (placebo) and multicenter. We will include patients 20-55 years of age with excessive and prolonged vaginal bleeding who are enrolled in Mostafa Khomeini hospital and Jamee Zanan(Mirza kpchak-khan) hospital as well as traditional medicine clinics. Inclusion criteria: Endometrial thickness in ultrasound is normal; Gynecologic examination is normal; The Pap smear is normal; concurrent hormonal therapy, herbal and other medicinal plants are not used; there is no chronic disease like diabetes, lupus and thyroid problems; there is no organic disease such as uterus or ovaries or other malignancies; Bleeding is more than 7 days and or Course is less than 21 days. Exclusion criteria: use of hormonal drugs in the study; Use of mefenamic acid in the study; Patients who require surgical intervention and have the other; bleeding during the study is so severe that emergency action is required. 15 patients will receive Myrtle fruit syrup and 15 will receive placebo. Syrup (drug and placebo) is used 3 times daily for a week starting menstruation and 1 tablespoon each half hour after a meal. The trend for 3 menstrual cycles (every month for 7 days) is repeated. Primary outcome: duration of menstruation and intensity of menstrual bleeding in each menstrual cycle is measured with the question of the number of pads used and the amount of hemoglobin before and end of the study are measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109077511N1**

Registration date: **2012-03-21, 1391/01/02**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-03-21, 1391/01/02

##### Registrant information

###### Name

Marzieh Qaraaty

###### Name of organization / entity

Golestan University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3254 1065

###### Email address

gharaaty1387@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Medical Faculty of Shahed University

##### Expected recruitment start date

2012-05-21, 1391/03/01

##### Expected recruitment end date

2013-08-20, 1392/05/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the Effect of Myrtus Communis L. (Myrtle) fruit syrup (B 438 syrup) in hypermenorrhea

##### Public title

The Effect of Myrtus Communis L. fruit syrup in women bleeding

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Patient satisfaction; outpatients aged 20- 55 years with excessive uterine bleeding that have a negative pregnancy test and they are not lactating; Endometrial thickness in ultrasound is normal; Gynecologic examination is normal; The Pap smear is normal; concurrent hormonal therapy, herbal and other medicinal plants are not used; there are no chronic disease like diabetes, lupus and thyroid problems; there is no organic disease such as uterus or ovaries or other malignancies; Intramural fibroids larger than 5 cm sub mucosal or not; Bleeding is more than 7 days and or Course is less than 21 days. Exclusion criteria: use of hormonal drugs in the study; Use of mefenamic acid in the study; Patients who are experiencing possible side effects; Patients who require surgical intervention and have the other; Patients with a personal request to withdraw from the study; bleeding during the study is so severe that emergency action is required.

### Age

From **20 years** old to **50 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical faculty of Shahed university

##### Street address

Abdollahzade St. Keshavarz blvd.

##### City

Tehran

##### Postal code

##### Approval date

2012-03-06, 1390/12/16

##### Ethics committee reference number

41/138342

## Health conditions studied

### 1

#### Description of health condition studied

hypermenorrhea

#### ICD-10 code

N92.0

#### ICD-10 code description

Excessive and frequent menstruation with regular cycle

## Primary outcomes

### 1

#### Description

Menstrual period duration

#### Timepoint

at the end of each cycle

#### Method of measurement

Questionnaire

### 2

#### Description

Intensity of menstrual bleeding

#### Timepoint

at the end of each cycle

#### Method of measurement

Questionnaire

### 3

#### Description

Hemoglobin

#### Timepoint

before & after the study

#### Method of measurement

cell counter

## Secondary outcomes

### 1

#### Description

drug side effect

#### Timepoint

at the end of study

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Syrup (drug), 3 times daily for a week starting menstruation, 1 tablespoon each half hour after meal. The trend for 3 menstrual cycles (every month for 7 days) is repeated.

#### Category

Treatment - Drugs

2

**Description**

Syrup (placebo), 3 times daily for a week starting menstruation, 1 tablespoon each half hour after meal. The trend for 3 menstrual cycles (every month for 7 days) is repeated.

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Mostafa khomeini hospital

**Full name of responsible person**

**Street address**

Italy St, khKeshavarz blvd

**City**

Tehran

2

**Recruitment center**

**Name of recruitment center**

traditional iranian medicine salamatgah, shahed university of medical science

**Full name of responsible person**

**Street address**

17,th. third dashtestan.Dr shariati St.

**City**

tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Medical faulty, Shahed University

**Full name of responsible person**

Dr. Heshmati

**Street address**

Abdollahzadeh st, Keshavarz blvd.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Medical faulty, Shahed University

**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**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Traditonal institue, Sahed University

**Full name of responsible person**

Marzieh Qaraaty

**Position**

PhD candidate of Traditionall Medicine

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahed university

**Full name of responsible person**

Marzieh Qaraaty

**Position**

PhD candidate of Traditionall Medicine

**Other areas of specialty/work**

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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*