

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

Tradional institue, Sahed University

Full name of responsible person

Marzieh Qaraaty

Position

PhD candidate of Traditionall Medicine

Other areas of specialty/work

Street address

Salamatgah, 17th, Dashtestan St, Dr Shariaty St.

City

Tehran

Postal code

Phone

+98 21 2288 2526

Fax

Email

gharaatyt1387@yahoo.com ,

gharaatyt1387@shahed.ac.ir

Web page address

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

Street address

Salamatgah, 17th, Dashtestan St, Dr. Shariaty St.

City

Tehran

Postal code

Phone

+98 21 2288 2521

Fax

Email

gharaatyt1387@yahoo.com ,

gharaatyt1387@shahed.ac.ir

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