Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
questionniare

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
Tradtional 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

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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