Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of comparison between frankincense (Boswellia serrata) capsule and ginger (Zingiber officinale) capsule on reducing heavy menstrual bleeding among women at the age of 18-45 years

Protocol summary

Summary

This study aimed to compare the effectiveness of ginger and frankincense on menstrual bleeding volume. This study is a randomized, double blind, multi-center clinical trial with placebo control. Inclusion criteria: Outpatient women at the age of 18-45 years with regular 22 to 35-day menstrual cycles suffering from heavy or prolonged menstrual bleeding; normal endometrial thickness in ultrasound; normal gynecologic examination; normal Pap smear; absence of moderate or severe anemia; not using hormonal drugs or any medication affecting menstrual bleeding (oral contraceptive pills and aspirin, warfarin). Exclusion criteria: severe bleeding which requires emergency measures; extreme skin sensitivity to frankincense or ginger. Intervention group 1: Frankincense capsule and ibuprofen tablet will be prescribed for the patients, three times a day, from first to the last day of menstrual period. This order will be followed in two consecutive cycles. Intervention group 2: Ginger capsule and ibuprofen tablet will be prescribed for the patients, three times a day, from first to the last day of menstrual period. This order will be followed in two consecutive cycles. Control group: Placebo capsule and ibuprofen tablet will be prescribed for the patients, three times a day, from first to the last day of menstrual period. This order will be followed in two consecutive cycles. Primary outcomes: the duration and severity of bleeding of menstrual periods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062228579N1**
Registration date: **2017-02-03, 1395/11/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-03, 1395/11/15

Registrant information

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Razieh Eshaghian
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Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison between frankincense (Boswellia serrata) capsule and ginger (Zingiber officinale) capsule on reducing heavy menstrual bleeding among women at the age of 18-45 years

Public title
Ginger capsule and frankincense effect on uterine hemorrhage
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Outpatient women at the age of 18-45years; Regular 22- 35 day menstrual cycles; presence of menorrhagia based on Higham bleeding assessment chart (bleeding more than 80 ml per cycle, or more than 7 days); absence of moderate or severe anemia (hemoglobin greater than 10.5 milligrams per deciliter); The absence of uterine fibroma or being smaller than 5 cm; The absence of ovarian cysts; Not using hormonal drugs or any medication affecting menstrual bleeding (oral contraceptive pills and aspirin, warfarin); normal endometrial thickness in abdominal or trans vaginal ultrasound; The patient is not pregnant or during lactation. Exclusion criteria: pregnancy; breast feeding; taking hormonal drugs or mefenamic acid during their menstruation period; being allergic to ginger or frankincense; severe bleeding during menstruation period requiring emergency measures.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
This study is a randomized, double-blind clinical trial (randomized block design permutations with blocks on volume 3)

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Isfahan University of Medical Sciencesl
Street address
Isfahan University of Medical Sciences, Hezar jarib street, Azadi square
City
Isfahan
Postal code
Approval date
2016-08-17, 1395/05/27
Ethics committee reference number
IR.MUI.REC.1395.30414

Health conditions studied

1

Description of health condition studied
Heavy menstrual bleeding
ICD-10 code
N92.0
ICD-10 code description
Excessive and frequent menstruation with regular cycle

Primary outcomes

1

Description
Menstrual blood volume
Timepoint
The end of each menstrual cycle
Method of measurement
Pictorial Blood Loss Assessment (PBAC)

2

Description
Time period (days) of menstrual bleeding
Timepoint
The end of each menstrual cycle
Method of measurement
Pictorial Blood Loss Assessment (PBAC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Frankincense capsule and ibuprofen tablet will be prescribed for the patients, three times a day, from first to the last day of menstrual period. This order will be followed in two consecutive cycles.
Category
Treatment - Drugs

2

Description
Intervention group 2: Ginger capsule and ibuprofen tablet will be prescribed for the patients, three times a

day, from first to the last day of menstrual period. This order will be followed in two consecutive cycles.

Category

Treatment - Drugs

3

Description

Control group: Placebo capsule and ibuprofen tablet will be prescribed for the patients, three times a day, from first to the last day of menstrual period. This order will be followed in two consecutive cycles.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital's gynecology clinic

Full name of responsible person

Razieh Eshaghian

Street address

Soffeh Boulevard

City

Isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital's gynecology clinic

Full name of responsible person

Razieh Eshaghian

Street address

Felezzi bridge, Shahid Motahari street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chacellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Mohammad Mazaheri

Street address

Traditional Medicine Department, Isfahan University of Medical Sciencesedical Science, Hezarjarib street

City

Isfahan

Grant name

Grant code / Reference number

395414

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

Yes

Title of funding source

Vice chacellor for research, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Razieh Eshaghian

Position

PHD student of TraditionalL Medicine

Other areas of specialty/work

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Person responsible for scientific 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