

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Name

Razieh Eshaghian

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 2512

###### Email address

r\_eshaghian@resident.mui.ac.ir

##### 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 committee of Isfahan University of Medical Sciences

##### 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 chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Mazaheri

**Street address**

Traditional Medicine Department, Isfahan University of Medical Sciences, 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 chancellor 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 Traditional Medicine

**Other areas of specialty/work****Street address**

Isfahan University of Medical Sciences, Hezar jarib street, Azadi square

**City**

Isfahan

**Postal code****Phone**

+98 31 3376 7525

**Fax****Email**

r\_eshaghian@resident.mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Mazaheri

**Position**

PhD, Assistance professor of Traditional Medicine

**Other areas of specialty/work****Street address**

Traditional Medicine Department, Isfahan University of Medical Sciences, Hezarjarib street

**City**

Isfahan

**Postal code****Phone**

+98 31 3792 8108

**Fax****Email**

mazaherimohammad@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Razieh Eshaghian

**Position**

PhD student of Traditional Medicine

**Other areas of specialty/work****Street address**

Traditional medicine group, Isfahan University of  
Medical Science, Hezarjarib street

**City**

Isfahan

**Postal code****Phone**

+98 31 3792 8108

**Fax****Email**

r\_eshaghian@resident.mui.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*