

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of topical ginger oil with oral ginger on the of menstrual flow

Protocol summary

2018-09-27, 1397/07/05

Study aim

The aim of this study was to evaluate the local effect of ginger oil with oral ginger on the amount of menstrual bleeding in healthy people.

Design

The sample size was 35 in each group. Then, patients are randomly divided into two groups receiving ginger capsules or ginger oil. This study is one side blind.

Settings and conduct

the person who examines the severity of the symptoms and the analyst is unaware of the intervention of the two groups. Both groups consume the drug for three consecutive menstrual cycles according to the same instructions (from two days before the onset of bleeding to the first three days of hemorrhage every 6 hours)

Participants/Inclusion and exclusion criteria

People with inclusion criteria include no history of ginger allergy, no history of bleeding disorders, no history of gallstones. In case of occurrence, Exclusion criteria include pregnancy, drug allergy and personality disorder

Intervention groups

Ginger Oil; edible ginger; Between two groups of students living in Shahid Beheshti dormitory

Main outcome variables

Menstrual bleeding in healthy people

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140902019012N3**

Registration date: **2018-09-27, 1397/07/05**

Registration timing: **retrospective**

Last update: **2018-09-27, 1397/07/05**

Update count: **0**

Registration date

Registrant information

Name

Pantea Shirooye

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 488 7140

Email address

pshirooye@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of topical ginger oil with oral ginger on the of menstrual flow

Public title

Comparing the effect of topical ginger oil with oral ginger on the of menstrual flow

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 45 years Regular menstruation at intervals of 21 to 35 days and regular bleeding for 3 to 10 days at least in the last three cycles Do not take other medications Lack of susceptibility to ginger No history of hemorrhagic diseases Lack of history of gallstone

Exclusion criteria:

Pregnancy Sensitization during the study Menstrual disorder; Do not use the medicine properly; Use of another drug not defined in the study Patients with severe potential side effects; Patients who need surgery and other interventions Patients who decide to leave the study with a personal request.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Random unit: Individual Randomization Tool: Random Numbers Because the form of the drug is not the same in the two groups, only the person who examines the severity of the symptoms and finally, the analyst of the intervention of the two groups is unaware.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is a blind side. Because the drug is not the same in the two groups. Only the person who examines the severity of the symptoms and ultimately the analyst is unaware of the intervention of the two groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical

Science, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

۶۱۵۳_۱۴۱۵۵

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.572

Health conditions studied**1****Description of health condition studied**

Menorrhagia

ICD-10 code

N92.0

ICD-10 code description

Excessive and frequent menstruation with regular cycle

Primary outcomes**1****Description**

Menstrual bleeding

Timepoint

cycle before intervention, every cycles during intervention (3 cycles)

Method of measurement

PBAC questionnaire

Secondary outcomes**1****Description**

side effect: Stomachache, nausea, vomiting, hematemesis, belch, fatigue, itching, acne, heartburn, diarrhea, constipation, melena, headache, drowsiness, redness, assessment of bleeding with PBAC

Timepoint

cycle before intervention, every cycle during intervention (3 cycles)

Method of measurement

questionnaire

Intervention groups**1****Description**

Ginger capsule, which is used for treatment and not placebo. Ingredients: Dried rhizome of ginger was prepared as needed to prepare ginger capsules. Each capsule is filled with 250 mg of ginger powder

Category

Treatment - Drugs

2

Description

Ginger Oil To grind ginger oil, ginger rhizomes are crushed and soaked in sesame oil in a ratio of one (ginger) to five (sesame oil). Then the oil becomes smooth. Microbial control tests include the determination of the total number of aerobic organisms and the absence of Salmonella, Pseudomonas, Staphylococcus and Ecoli.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti university campus

Full name of responsible person

Mrs. Zaem

Street address

Shams Alleg., Vali-eAsr Ave., Tehran., Iran

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14155-6153

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+98 21 8877 3521

Email

pshirooye@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Iranian Traditional Medicine of Shahid Beheshti University of Medical Science

Full name of responsible person

Somaye Esmaeili

Street address

Shams Alley, Vali-e Asr Ave, Tehran, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

School of Iranian Traditional Medicine of Shahid Beheshti University of Medical Science

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pantea Shirooye

Position

Traditional medicine PHD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The questionnaires used and the information about the main outcome after the 3 months of publication of the results are shared with the applicants.

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

Researchers working in institutions academic and scientific

Under which criteria data/document could be used

Students doing thesis Research centers

From where data/document is obtainable

pantea shirooye pshirooye@sbmu.ac.ir Tell: 88773521

What processes are involved for a request to access data/document

After 6 months of sampling and 2 months of statistical analysis and 3 months after printing results It takes about 14 months to complete. Information is provided to the applicant

Comments