Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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
2018-09-27, 1397/07/05

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, nasea, 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

City
Tehran

Province
Tehran

Postal code
14155-6153

Phone
+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

City
Tehran

Province
Tehran

Postal code
14155-6153

Phone
+98 21 8877 3521

Email
pshirooye@sbmu.ac.ir

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

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

City
Tehran

Province
Tehran

Postal code
14155-6153

Phone
+98 21 8877 3521

Fax

Email
pshirooye@sbmu.ac.ir

Web page address

Person responsible for scientific 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

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

City

Tehran
Province
Tehran
Postal code
14155-6153
Phone
+98 21 8877 3521
Fax
Email
pshirooye@sbmu.ac.ir
Web page address

Person responsible for updating data

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
Street address
Shams Alley, Vali-e Asr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14155-6153
Phone
+98 21 8877 3521
Fax
Email
pshirooye@sbmu.ac.ir
Web page address

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