Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the Effect of Matricaria Chamomile and Rhus Coriaria on Some Uterine Fibroma Symptoms in Women with fibroid diseases

Protocol summary

Study aim
Help to reduce the use of hormone therapy and analgesics and improve the quality of life for women with the least complicated drugs

Design
This study is a clinical trial study with a control group, with parallel groups, three blinded, randomized, that will use the chamomile and chamomile capsules as the intervention group and lactose capsules for placebo. These capsules have the same shape and size at a dose of 500 mg and are quite similar to each other, with a sample size of 183 patients.

Settings and conduct
The place of research is the Faghihi and Zainabiyyeh hospitals and the Motahari clinic. Patient will be randomly assigned into three intervention groups, the researcher, patient, and analyzer are blinded

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.Women with fibroid disease confirmed 2.Women who are willing to cooperate and have submitted their written consent 3. Not taking any hormone medication 4.The patient is not involved in any other disease 5. not be pregnant 6. not be lactating 7. Not allergic to chamomile and chamomile and mefenamic acid 8. No history of gastrointestinal, liver, brain and kidney disease and coagulation disorders 9.Body Mass Index 19-29 10. Age range 20-49 years 11.No history of prolonged constipation Exclusion criteria:1.Allergic reaction to the drug 2. People with asthma 3.People taking anticoagulants 4. People taking benzodiazepine drugs5. People who drink alcohol 6.People who become pregnant during the study 7. Disease exacerbation during the study when the patient requires hormone therapy 8. People who are sensitive to lactose

Intervention groups
The three intervention groups in this study consisted of 500 mg chamomile, sumac and placebo capsules, each administered three times daily

Main outcome variables
Pain; Bleeding; Urinary Frequency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200113046115N1**
Registration date: **2020-03-21, 1399/01/02**
Registration timing: **prospective**

Last update: **2020-03-21, 1399/01/02**
Update count: **0**

Registration date
2020-03-21, 1399/01/02

Registrant information

Name
maryam jafari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 77 3425 0884
Email address
jafari_ma@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effect of Matricaria Chamomile and Rhus Coriaria on Some Uterine Fibroma Symptoms in Women with fibroid diseases

Public title
The Effect of Matricaria Chamomile and Rhus Coriaria on some Uterine Fibroma Symptoms in Women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with Fibroid Disease Confirmed by a Gynecologist Women who are willing to Cooperate and Submit Their Written Consent Not taking any Hormonal Medication The patient is not involved in any other diseases, including thyroid disease, endometriosis, adenomyosis and malignancies, etc. (Based on patient records) Don't be pregnant Don't be lactating Not Allergic to Chamomile and Sumac and Mefenamic Acid No History of Gastrointestinal, liver, Brain and Kidney Disease and Coagulation disorders Body Mass Index 19-29 Age range 20-49 years No history of prolonged constipation

Exclusion criteria:

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **183**

Randomization (investigator's opinion)
Randomized

Randomization description
Divide the block into three groups A, B, C and each letter is randomly assigned to the sumac, chamomile, and placebo group. The letters are then grouped into 6 (1: ABC, 2: ACB, 3: BAC, 4: BCA, 5: CBA, 6: CAB) and A number is randomly selected from 1 to 6, indicating the order of allocation of the first three individuals in the groups. Again, 1 to 6 numbers are selected at random. The order of assignment of individuals to groups is specified at each time

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the capsules of the same size and color in dark color packages will be prepared by the pharmacology unit of Shiraz University of Medical Sciences.Medicines with specific codes that only the pharmacist is aware of and The researcher is the prescriber and the participant is unaware.The data analyzer is also uninformed. In this study, only the pharmacist is aware of the type of medication

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of shiraz university of medical science

Street address
Central building of Shiraz university of Medical Science ,Zand Ave,Across Palestin Street

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2019-12-31, 1398/10/10

Ethics committee reference number
IR.SUMS.REC.1398.1199

Health conditions studied

1

Description of health condition studied
Uterine Fibroma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Moderate to severe pain

Timepoint
Before intervention and 2 months after intervention

Method of measurement
Pain measurement by using visual analogue scale

2

Description
Bleeding includes menorrhagia and menometrorrhagia

Timepoint
Before intervention and 2 months after intervention

Method of measurement
Using a pictorial blood assessment chart, patient with the

bleeding score higher than 100 will study The pre-study and post-study scores will be compared

3

Description
Frequent urination more than 7 times a day
Timepoint
Before intervention and 2 months after intervention
Method of measurement
urination will be entered into the study more than 7 times a day and the number of urination before and after the intervention will be questioned and recorded and compared by the patient

Secondary outcomes

empty

Intervention groups

1

Description
500 mg Matricaria chamomile capsule standardized by Barij Essence Company and packaged by Shiraz University of Medical Sciences Pharmacology Unit and medication duration three times daily for two menstrual cycles for the first seven days of menstruation.
Category
Treatment - Drugs

2

Description
The 500 mg Sumac Rus Coriaria capsule is standardized and packaged by the Shiraz University of Medical Sciences Pharmacology Unit and is administered three times daily during the first seven menstrual cycles of the menstrual cycle.
Category
Treatment - Drugs

3

Description
Control group: 500 mg placebo capsule containing cellulose powder packaged by Shiraz University of Medical Sciences pharmacology unit and drug administration three times daily during two menstrual cycles for the first seven days of menstruation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
Dr.Mohammad Vahid Joraat
Street address
Zand St, Shiraz، Fars Province
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3235 1087
Email
Faghihihsp@sums.ac.ir

2

Recruitment center
Name of recruitment center
Zeiynabiyyeh haspital
Full name of responsible person
Dr.Navid Omidifar
Street address
Zeynabiyeh Blv، Shiraz، Fars Province
City
Shiraz
Province
Fars
Postal code
715381311
Phone
+98 71 3726 6811
Email
Zeinabhp@sums.ac.ir

3

Recruitment center
Name of recruitment center
Motahari clinic
Full name of responsible person
Dr.Mani Ramzi
Street address
Next to Namazi Hospital,Karim Khan Zand Blvd, Shiraz, Fars Province
City
Shiraz
Province
Fars
Postal code
71473771438
Phone
+98 71 3612 1000
Email
Motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Dr Gholamreza Hatam

Street address

Central Building of Shiraz University of Medical Science, Zand Street, Shiraz, Fars province

City

Shiraz

Province

Fars

Postal code

71345- 1978

Phone

+98 71 1212 2633

Fax

+98 71 1212 2430

Email

info@sums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Marziyeh Akbarzadeh

Position

Professor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Fars

Postal code

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Jafari

Position

Student of Master of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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City

Shiraz

Province

Fars

Postal code

111111111

Phone

+98 77 3425 0884

Email

maryam.jafari9170@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Jafari

Position

Student of Master of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

6 Block, Eram dormitory, Eram sq

City

Shiraz

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111111111

Phone

+98 77 3425 0884

Email

maryam.jafari9170@gmail.com

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

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

Analytic Code

Yes - There is 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

After analyzing the data and after Identifying people, part of the data will be available as a pdf file

When the data will become available and for how long

3 Month After Finish of Study

To whom data/document is available

Researchers are working in university centers

Under which criteria data/document could be used

No data can be used under any circumstances

From where data/document is obtainable

Referring to Professor Marziyeh Akbarzadeh

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

Visit the Faculty of Nursing and Midwifery of Professor Akbarzadeh's office

Comments