

# 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 drugs 5. 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**

Zeinyabiyyeh 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**

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**Province**

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71345- 1978

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**Fax**

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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

**Street address**

Faculty of Midwifery and Nursing, Namazi Square

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**Email**

AKBARZADEHMARZIEH@YAHOO.COM

**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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**Province**

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**Phone**

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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

**Province**

Fars

**Postal code**

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**