

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Ultrasonographic study of the effects of the herbal medicine package on the size of fibroma

#### Protocol summary

##### Study aim

Ultrasonographic study of the effects of the herbal medicine package on the size of fibroma

##### Design

The study of the two-course clinical trial of 60 patients was randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

##### Settings and conduct

Patients with With fibroids in Arak radiology clinic in Arak are divided into 2 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:15 to 49 years, having a uterine fibroid smaller millimetre, no history of uterine cancer in the individual and first-degree relatives, no pregnancy, no breastfeeding, lack of uterine bleeding, colitis, hemorrhoids, appendicitis, intestinal obstruction, acute inflammatory bowel diseases such as Crohn's disease, ulcerative colitis, abdominal pain of unknown origin, gastric bleeding and esophageal varices Absence of underlying disease Exclusion criteria:Dissatisfaction

##### Intervention groups

Intervention group: One capsule of Iraj Fiqra 500 milligram at the end of the night with warm water and soda soda as a decoction in the morning and night (half an hour before breakfast and the night before bed take a bag of medicine in a glass of water for 10 minutes Boil over low heat and drink until hot. Control group: placebo, which is in the form of a capsule similar to Iraj Fiqra medicine (in coordination with the pharmaceutical company, is poured into capsules similar to Iraj Fiqra flour) and black tea tea is used to replace placebo for soda.

##### Main outcome variables

Fibroma size

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N147**

Registration date: **2020-07-14, 1399/04/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-07-14, 1399/04/24**

Update count: **0**

##### Registration date

2020-07-14, 1399/04/24

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-04, 1399/03/15

##### Expected recruitment end date

2021-07-06, 1400/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Ultrasonographic study of the effects of the herbal medicine package on the size of fibroma

## Public title

Ultrasonographic study of the effects of the herbal medicine package on the size of fibroma

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

15 to 49 years Having a uterine fibroid smaller millimetre No history of uterine cancer in the individual and first-degree relatives No pregnancy No breastfeeding Lack of uterine bleeding, colitis, hemorrhoids, appendicitis, intestinal obstruction, acute inflammatory bowel diseases such as Crohn's disease, ulcerative colitis, abdominal pain of unknown origin, gastric bleeding and esophageal varices Absence of underlying disease

### Exclusion criteria:

Dissatisfaction

## Age

From **15 years** old to **49 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple individual randomization with randomization with envelopes in 2 groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is clinical trial. Outcome evaluator and analyzer and participant are blind (double blind). Outcome evaluator and analyzer and participant don't aware from grouping.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2020-05-31, 1399/03/11

#### Ethics committee reference number

IR.ARAKMU.REC.1399.091

## Health conditions studied

### 1

#### Description of health condition studied

Uterine fibroids

#### ICD-10 code

O34.1

#### ICD-10 code description

Maternal care for benign tumor of corpus uteri

## Primary outcomes

### 1

#### Description

Fibroma size

#### Timepoint

Before and after three months of treatment

#### Method of measurement

Sonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: One capsule of Iarj Fiqra 500 milligram at the end of the night with warm water and soda as a decoction in the morning and night (half an hour before breakfast and the night before bed take a bag of medicine in a glass of water for 10 minutes Boil over low heat and drink until hot.

**Category**

Treatment - Drugs

**2****Description**

Control group: placebo, which is in the form of a capsule similar to Iraj Fiqra medicine (in coordination with the pharmaceutical company, is poured into capsules similar to Iraj Fiqra flour) and black tea tea is used to replace placebo for soda.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Private outpatient Radiology Clinic

**Full name of responsible person**

Dr Fatemeh Safi

**Street address**

Shariati square, Arak

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f.safi@arakmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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aliakamliir@yahoo.com

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mehdi Salehi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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Emam reza clinic, Shahid Shirodi street

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m.salehi@arakmu.ac.ir

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

Arak University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Safi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiology

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Valiasr Hospital, Valiasr square, Shahid Shirodi street

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saf@arakmu.ac.ir  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Seyed Majid Aghvami  
**Position**  
Resident of radiology  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Emergency Medicine  
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Payambar Azam Complex, Basij square, Sardasht,  
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848176941  
**Phone**  
+98 86 3222 2003

**Email**  
Majidaghvami@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

Yes - There is 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

When we publish article in journal

### When the data will become available and for how long

After the article is published

### To whom data/document is available

Researcher in university

### Under which criteria data/document could be used

If there are additional questions

### From where data/document is obtainable

Dr Fatemeh Safi

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

They have to write letters to the professors and the university.

### Comments