Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Iarj 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

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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 elevator and analyzer and participant are blind (double blind).Outcome elevator 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 comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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 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
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Shariati squre,Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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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
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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
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Dr Seyed Majid Aghvami
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Resident of radiology
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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
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