Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparing the effects of Berberine, Curcumine and gonadotropin-releasing hormone agonist (GnRH) on uterine leiomyoma volume , a controlled, randomized clinical trials

Protocol summary

Study aim

Comparison of the effect of curcumin and berberine and gonadotropin-releasing hormone (GnRH) agonists on uterine myoma size and hormonal changes and hot flashes

Design

Clinical trial in three parallel groups, not blinded, randomized, phase 3 on 102 patients. To randomize permutation blocks

Settings and conduct

Women aged 18 to 45 years who have a uterine myoma larger than 5 cm and if there are more, other myomas are smaller than 2 cm and refer to the clinic of Amir Al-Momenin Hospital in Semnan. According to the admission criteria, 102 patients will be randomly assigned using the randomized permutation block method and will be divided into three groups treated with curcumin, berberine and leoporline. After identifying the myoma with vaginal ultrasound, its volume is performed at the beginning and at weeks 6 and 12, and their average is also calculated. Serum samples (FSH, LH, E2) is measured at baseline and at 12 weeks after starting treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 18 to 45 years old have a myoma larger than 5 cm that has another myoma (s) (if any) less than 2 cm in size - Exclusion criteria: 1) Women with extra myoma (s) greater than or equal to 2 cm or myoma with a size of 2-5 cm 2) Women who have been treated with any type of estrogen or progesterone in less than one month, hormonal implants in the last 3 months, any type of antihypertensive drug, have had major medical disease, previous treatment or surgery for myoma or during the study Complications have been reported

Intervention groups

Patients with uterine myoma who have referred to the gynecological clinic of Amir Al-Momenin Hospital and are treated with curcumin, berberine and leoporline in three groups

Main outcome variables

Uterine myoma size, LH, FSH, E2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220201053908N1**
Registration date: **2022-02-23, 1400/12/04**
Registration timing: **prospective**

Last update: **2022-02-23, 1400/12/04**
Update count: **0**

Registration date

2022-02-23, 1400/12/04

Registrant information

Name

Elham Akbari Vafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-06, 1400/12/15

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of Berberine, Curcumine and gonadotropin-releasing hormone agonist (GnRH) on uterine leiomyoma volume , a controlled, randomized clinical trials

Public title
Comparing the effects of Berberine, Curcumine and gonadotropin-releasing hormone agonist (GnRH) on uterine leiomyoma volume
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non-menopausal women between the ages of 18 and 45, who have a myoma larger than 5 cm that have abnormal uterine bleeding, pelvic pain, dysmenorrhea, and a compressive effect. Women with myomas larger than or equal to 5 cm who have other myomas (s) less than 2 cm in size
Exclusion criteria:
Women with extra myoma (s) greater than or equal to 2 cm Women with uterine myoma who have been treated with any type of estrogen or progesterone in less than a month and hormonal implants in the last 3 months Women with a history of major medical illness and / or previous drug or surgical treatment of uterine leiomyomas All women with myomas 2-5 cm in size were excluded from the study Patients receiving antihypertensive drugs, beta-blockers and calcium channel blockers, and ACE inhibitors were excluded from the study due to possible drug interactions Patients who develop side effects during the study will be excluded from the study
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment will be done using the randomized permutation block method. The three study groups are named A, B and C and are written randomly in triplicate blocks and the order list of groups is provided to us. This will be done by a statistical study consultant who is not present at the clinical trial.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Siences
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini St., Imam Hossein Square
City
Semnan
Province
Semnan
Postal code
3519734731
Approval date
2022-01-24, 1400/11/04
Ethics committee reference number
Ir.semums.rec.1400.304

Health conditions studied

1

Description of health condition studied
Uterine myoma
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Uterine myoma size
Timepoint
At the beginning of the study and 6 and 12 weeks after starting treatment
Method of measurement
Vaginal ultrasound machine

Secondary outcomes

1

Description
LH hormon
Timepoint

At the beginning of the study and 12 weeks after treatment

Method of measurement

RIA laboratory method

2

Description

FSH hormon

Timepoint

At the beginning of the study and 12 weeks after treatment

Method of measurement

RIA laboratory method

3

Description

Estradiol hormon

Timepoint

At the beginning of the study and 12 weeks after treatment

Method of measurement

RIA laboratory method

Intervention groups

1

Description

Intervention group: The first group treated with curcumin, each tablet contains 450mg of turmeric rhizome powder and 50mg of turmeric extract, which is standardized based on 5.47mg of curcumin. Once a day, one tablet, made by Dineh Company

Category

Treatment - Drugs

2

Description

Intervention group: The second group treated with berberine capsule, 1000mg pure berberine extract extracted from barberry plant. One capsule twice a day, Omid Parsina Damavand Company

Category

Treatment - Drugs

3

Description

Control group: The third group treated with leuprorelin acetate in the form of an ampoule containing 3.75 mg of leuprorelin acetate by subcutaneous or intradermal injection of one dose per month, made by Varian Pharmed Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Elham Akbari

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini St., Imam Hossein Square

City

Semnan

Province

Semnan

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3519734731

Phone

+98 23 3346 0055

Email

amir.hospital@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr majid mir mohammadkhani

Street address

Vice Chancellor for Research and Technology, Headquarters of Semnan University of Medical Sciences, Basij Blvd.

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3514799442

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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

Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Elham saffarieh

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Amir Al-Momenin Hospital, Shahid Mostafa Khomeini Boulevard, Imam Hossein Square

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eli_saffarieh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Elham saffarieh

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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