

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 leporline. 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 leporline 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)

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+98 23 3346 0066

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elak_ir222@yahoo.com

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

AgeFrom **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

lr.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 leuporelin acetate in the form of an ampoule containing 3.75 mg of leuporelin 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

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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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rds@semums.ac.ir

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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Elham Akbari Vafaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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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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