

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The effect of oral Mullein capsules (*Verbascum Sp*) on uterine leiomyomas size and the amount of menstrual bleeding in women with asymptomatic leiomyomas : a triple blind randomised controlled trial.

Protocol summary

Study aim

Aims: Determining the effect of the oral Mullein capsules (*Verbascum Sp*) on the size of uterine leiomyoma and the amount of menstrual bleeding in women with asymptomatic uterine leiomyomas.

Design

Study design: randomized, triple-blind, placebo-controlled (the assessor, participants, and data analyzer will be unaware of the type of intervention given to every participant). Sample size: 50 persons, 25 as the intervention group and 25 in the control group. Intervention Study: The women in Intervention group will receive 400 mg oral mullein capsules twice a day for two months. Women in the control group, will receive in similar route to intervention group.

Settings and conduct

Iran-Tabriz, AlzahraTherapeutic Educational Center

Participants/Inclusion and exclusion criteria

Study population: women with asymptomatic uterine leiomyoma that Higham score before intervention is below 100. Inclusion criteria: age 18-50 years, women with at least one asymptomatic uterine fibroid larger than 2.5 cm. Exclusion criteria: pregnancy and lactation, desire to become pregnant during the next three months, uterine leiomyoma in size more than 12 cm, the size of the uterine leiomyoma equal or more than 20 weeks of gestation, anemia requiring treatment, history of chronic diseases and concurrent use of other medications or herbal remedies, history of previous surgery such as myomectomy, use of hormonal therapy in the last three months, presence of a hormonal IUD, Allergy to treatment.

Intervention groups

The women in Intervention group will receive 400 mg oral mullein capsules twice a day for two months women in control group will receive 400 mg placebo capsules (containing Flour) twice a day for two months

Main outcome variables

Uterine leiomyomas Menstrual bleeding loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012827311N2**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **prospective**

Last update: **2018-05-16, 1397/02/26**

Update count: **1**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Behnaz Sadeghzadeh Oskouei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral Mullein capsules (*Verbascum Sp*) on uterine leiomyomas size and the amount of menstrual bleeding in women with asymptomatic leiomyomas : a triple blind randomised controlled trial.

Public title

The effect of oral Mullein capsules on the treatment of uterine leiomyomas.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Willingness to participate in the study, having a literate and able to answer the questions, women of reproductive age 18-50 years with asymptomatic uterine leiomyomas that confirmed by abdominal ultrasound (at least one leiomyoma largest than 2.5 cm), women with normal menstruation (35-21 days).

Exclusion criteria:

Exclusion criteria: Pregnant and lactating women, desire to become pregnant during the next three months, uterine leiomyoma in size more than 12 cm, the size of the uterine leiomyoma equal or more than 20 weeks of gestation, anemia requiring treatment, history of chronic diseases (such as heart disease, thyroid, etc.) and concurrent use of other medications or herbal remedies, history of previous surgery such as myomectomy, use the OCP or other methods of hormone therapy during the last three months, presence of a hormonal IUD, known diseases of the genital tract, Allergy to treatment.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment Sequence was determined using Random Computer Software (Random Allocation Software) through blocks 4 and 6 with a one to one assignment ratio. To conceal the allocation of capsules containing drugs and medicines, they were placed in the same packets of a matt burst numbered. Envelopes are

numbered from 1 to 50. Sequencing and preparation of packets numbered by the person not involved in the collection and analysis of data was carried out.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To conceal the allocation of capsules containing drugs and medicines, they were placed in the same packets of a matt burst numbered. Envelopes are numbered from 1 to 50. Sequencing and preparation of packets numbered by the person not involved in the collection and analysis of data was carried out. . In this study, the participants, the researcher and the person who examined the outcome (radiologist) were blinded to the intervention assigned to the participants.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue,

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Tabriz

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East Azarbaijan

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5166614766

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.TBZMED.REC.1395.1131

Health conditions studied**1****Description of health condition studied**

Uterine leiomyomas

ICD-10 code

D25.9

ICD-10 code description

Leiomyoma of uterus -Leiomyoma of uterus, unspecified

Primary outcomes

1

Description

Size of Uterine Liomyoma

Timepoint

before intervention and 2 month after intervention

Method of measurement

Sonography study

2

Description

Menstrual bleeding loss

Timepoint

before intervention and 4 ,8 weeks after intervention

Method of measurement

Pictorial Blood Loss Assessment Chart (PBAC)

Secondary outcomes

1

Description

haemoglobin

Timepoint

before intervention and 2 months after intervention

Method of measurement

blood exam

2

Description

size of uterine

Timepoint

before intervention and 2 months after intervention

Method of measurement

Sonography study

3

Description

Side events

Timepoint

two months after intervention

Method of measurement

Checklist of side events

4

Description

Satisfaction with treatment received

Timepoint

two months after intervention

Method of measurement

Checklist of Satisfaction with treatment received

Intervention groups

1

Description

The women in Intervention group will receive 400 mg oral mullein capsules twice a day for two months

Category

Treatment - Drugs

2

Description

women in control group will receive 400 mg placebo capsules (containing flour) twice a day for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AlzahraTherapeutic Educational Center

Full name of responsible person

Nafiseh Ghassab Abdollahi, MSc Student of Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Nafiseh Ghassab Abdollahi

Position

MSc Student of Midwifery

Latest degree

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Other areas of specialty/work

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No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available