

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of plant Royan vaginal cream for the treatment of myoma with placebo

Protocol summary

s.houshmandi@arums.ac.ir

Summary

The comparison of effect vaginal herbal cream with placebo in fibroma treatment, Random, Clinical triple blind trial , Women in fertility age (18-45 years old) having fibroma (receiving embryo vaginal cream) and control group (receiving placebo vaginal cream) as follow: - The intervening group (45 ones) who shall receive embryo vaginal cream from the first day of menstruation for two periods; 3 applicators each night - Placebo group (45 ones) who shall receive the placebo vaginal cream from first day of menstruation for two periods; 3 applicators each night. Then effect of embryo vaginal cream on dimensions of uterine fibroma, amount of bleeding, and life quality of women will be measured.

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042217388N1**

Registration date: **2015-08-15, 1394/05/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-08-15, 1394/05/24

Registrant information

Name

Sousan Houshmandi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2006

Email address

Scientific title

Effect of plant Royan vaginal cream for the treatment of myoma with placebo

Public title

Effect of plant of Royan vaginal cream for the treatment of myoma with placebo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : All women of childbearing age (45 to 18) with at least one Fybrm to1 cm or larger, which is confirmed by ultrasound. Have a negative pregnancy test. Exclusion criteria : 1. Patients who have had hormone therapy 6 months before the treatment. 2. Patients who have had surgeries before, such as: Myomectomy. 3. Requires immediate surgical. 4. Pregnancy during the treatment 5.Abnormal Pap-Asmyr or severe anemia (8/0)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah St,
Ardabil, Iran

City

Ardabil

Postal code

56189-53141

Approval date

2014-04-14, 1393/01/25

Ethics committee reference number

43/525

Health conditions studied

1

Description of health condition studied

Leiomyoma

ICD-10 code

D25

ICD-10 code description

Leiomyoma of uterus

Primary outcomes

1

Description

Reduction in bleeding volume of Myoma

Timepoint

Before and after treatment

Method of measurement

Submit in Higam table

Secondary outcomes

1

Description

The pain of Myoma

Timepoint

Before and after intervention

Method of measurement

VAS measurement

2

Description

Size of the Myoma

Timepoint

Before and after intervention

Method of measurement

Sonography

3

Description

Life style

Timepoint

Before and after intervention

Method of measurement

Questionnaire Code SF36

Intervention groups

1

Description

Intervention: From the first day of menstruation, using of Royan vaginal cream full 3 applicator per night for 2 periods.

Category

Treatment - Drugs

2

Description

Control: From the first day of menstruation, using of Placebo vaginal cream full 3 applicator per night for 2 periods.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Sousan Houshmandi, Member of faculty

Street address

Alavi Hospital, Maadi st, Ayatollah Moghaddas Ardabili
St, Ardabil

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences.

Full name of responsible person

Firouzeh Asadzadeh

Street address

Daneshgah St, Ardabil University of Medical Science

City

Ardabil

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences.

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Bu Ali Company of Drugs Production

Full name of responsible person

Ali Reza Masoumi

Street address

No 47, No 6 Alley, Shahid DelAzar St, Qom

City

Qom

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bu Ali Company of Drugs Production

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Sousan Houshmandi

Position

Master of Science Midwife

Other areas of specialty/work

Street address

Ardabil University of Medical Sciences

City

Ardabil

Postal code

56189-53141

Phone

+98 45 3351 0052

Fax

+98 45 3351 8939

Email

hh4880@yahoo.com

Web page address

www.arums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Sousan Houshmandi

Position

Master of Midwifery

Other areas of specialty/work

Street address

Ardabil University of Medical Sciences

City

Ardabi

Postal code

56189-53141

Phone

+98 45335100523

Fax

+98 45 3351 8939

Email

hh4880@yahoo.com

Web page address

www.Medicdne.arums.ac.ir

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty