

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of fennel supplement versus no supplement on the number of ovarian follicles, the endometrial diameter and ovarian volume in infertile women: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of fennel supplement versus no supplement on the number of ovarian follicles, the endometrial diameter and ovarian volume in infertile women. **Design:** A single blind randomized clinical trial. **Setting and conduct:** The eligible women who are candidate for IVF and will refer to Infertility Clinic of Fatemiah Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** (a) being infertile; (b) being candidate for IVF; (c) age of 15 to 45 years. **Exclusion criteria:** Having severe endometriosis. **Intervention group:** (a) Routine medications for stimulating ovulation plus oral fennel supplement 10 mg daily for two months; (b) Routine medications for stimulating ovulation plus oral fennel supplement 10 mg daily for two months. **Control group:** Routine medications for stimulating ovulation for two months. **Primary outcome:** (a) measuring the number of ovarian follicles before and two months after treatment using ultrasonography; (b) measuring the endometrial diameter before and two months after treatment using ultrasonography; (c) measuring the ovarian volume before and two months after treatment using ultrasonography. **Secondary outcome:** Nothing. **Randomization:** The patients will be randomly assigned to intervention groups using block randomization of 9 groups. **Blinding:** The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509069014N78**

Registration date: **2015-09-08, 1394/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-08, 1394/06/17

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fennel supplement versus no supplement on the number of ovarian follicles, the endometrial diameter and ovarian volume in infertile women: a single blind randomized clinical trial

Public title

Effect of fennel supplement versus no supplement on the number of ovarian follicles, the endometrial diameter and ovarian volume in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) being infertile; (b) being candidate for IVF. Exclusion criteria: Having severe endometriosis

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention groups using block randomization of 9 groups. Blinding: The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-08-17, 1394/05/26

Ethics committee reference number

IR.UMSHA.REC.1394.258

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

measuring the number of ovarian follicles

Timepoint

before and two months after treatment

Method of measurement

using ultrasonography

2

Description

measuring the endometrial diameter

Timepoint

before and two months after treatment

Method of measurement

using ultrasonography

3

Description

measuring the ovarian volume

Timepoint

before and two months after treatment

Method of measurement

using ultrasonography

Secondary outcomes

1

Description

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups

1

Description

Routine medications for stimulating ovulation plus oral
fennel supplement 10 mg daily for two months

Category

Treatment - Drugs

2

Description

Routine medications for stimulating ovulation plus oral fennel supplement 10 mg daily for two months

Category

Treatment - Drugs

3

Description

Routine medications for stimulating ovulation for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Mahnaz Yavangi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

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

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Full name of responsible person

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Full name of responsible person

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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Web page address**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