

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of using extract of foeniculum vulgare with induction ovulation versus induction ovulation alone on pregnancy outcomes through invitro fertilization in infertile women with poor ovarian response: a before after clinical trial

#### Protocol summary

##### Summary

**Objectives:** To assess the effect of using extract of foeniculum vulgare with induction ovulation versus induction ovulation alone on pregnancy outcomes through invitro fertilization in infertile women with poor ovarian response. **Design:** a before after clinical trial. **Setting and conduct:** The eligible infertile women who are admitted in infertility department of Fatemieh Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** (a) infertility with poor ovarian response; (b) age of 35 years; (c) FHS equal to or greater than 10 mIU/ml on the third day of menstrual period; (d) ovarian volume equal to or greater than 3 ml; (e) history of unsuccessful IVF; (f) number of ovules less than 3 to 5. **Exclusion criteria:** (a) FSH more than 20 mIU/ml on the second to fourth days of menstrual period; (b) women with uterine anomaly or obstruction of uterine tube; (c) using corticosteroid during the last 5 months; (d) contraindication of pregnancy; (e) missing of one ovary; (f) systemic diseases such as diabetes, adrenal dysfunction, hypothalamus tumor, hyperprolactinemia, and intracranial damages. **Intervention:** drinking 200 ml extract of foeniculum vulgare daily for 2 months and then induction ovulation. **Control:** induction ovulation alone. **Primary outcome:** (a) number of follicles before and 2 months after intervention using ultrasonography; (b) number of ovule before and 2 months after intervention using microscope; (c) number of fetus before and 2 months after intervention using microscope; (d) number of pregnancy before and 2 months after intervention using ultrasonography. **Secondary outcome:** (a) number of receiving HMG before and 2 months after intervention through checking medical record; (b) number of induction before and 2 months after intervention through checking medical record.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411269014N48**

Registration date: **2014-12-02, 1393/09/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-02, 1393/09/11

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of using extract of foeniculum vulgare with induction ovulation versus induction ovulation alone on pregnancy outcomes through invitro fertilization in infertile women with poor ovarian response: a before after clinical trial

**Public title**

Effect of using extract of foeniculum vulgare with induction ovulation versus induction ovulation alone on pregnancy outcomes through invitro fertilization in infertile women with poor ovarian response

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: (a) infertility with poor ovarian response; (b) age of 35 years; (c) FHS equal to or greater than 10 mIU/ml on the third day of menstrual period; (d) ovarian volume equal to or greater than 3 ml; (e) history of unsuccessful IVF; (f) number of ovules less than 3 to 5. Exclusion criteria: (a) FSH more than 20 mIU/ml on the second to fourth days of menstrual period; (b) women with uterine anomaly or obstruction of uterine tube; (c) using corticosteroid during the last 5 months; (d) contraindication of pregnancy; (e) missing of one ovary; (f) systemic diseases such as diabetes, adrenal dysfunction, hypothalamus tumor, hyperprolactinemia, and intracranial damages.

**Age**

From **35 years** old to **45 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **15**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

Randomization: This is a before after trial therefore randomization is impossible. Blinding: Blinding is impossible.

**Secondary Ids**

empty

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

Research Ethic Committee of Hamadan University of Medical Sciences

**Street address**

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

**City**

Hamadan

**Postal code**

6517838695

**Approval date**

2014-06-25, 1393/04/04

**Ethics committee reference number**

D/P/16/35/9/1540

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

infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

**Primary outcomes****1****Description**

number of follicles

**Timepoint**

before and 2 months after intervention

**Method of measurement**

using ultrasonography

**2****Description**

number of ovule

**Timepoint**

before and 2 months after intervention

**Method of measurement**

using microscope

**3****Description**

number of fetus

**Timepoint**

before and 2 months after intervention

**Method of measurement**

using microscope

## 4

### Description

number of pregnancy

### Timepoint

before and 2 months after intervention

### Method of measurement

using ultrasonography

## Secondary outcomes

### 1

#### Description

number of receiving HMG

#### Timepoint

before and 2 months after intervention

#### Method of measurement

through checking medical record

### 2

#### Description

number of induction

#### Timepoint

before and 2 months after intervention

#### Method of measurement

through checking medical record

## Intervention groups

### 1

#### Description

drinking 200 ml extract of foeniculum vulgare daily for 2 months and then induction ovulation

#### Category

Treatment - Drugs

### 2

#### Description

induction ovulation alone

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatemieh Hospital

##### Full name of responsible person

Dr Elnaz Mohammadai

##### Street address

Fatemieh Hospital, Pasdaran Ave.

##### City

Hamadan

## 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

##### City

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

Fatemieh Hospital

##### Full name of responsible person

Dr Elnaz Mohammadai

##### Position

Resident of Obstetrics

##### Other areas of specialty/work

##### Street address

Fatemieh Hospital, Pasdaran Ave.

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+98 81 8287 7459

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el.mohamadi@umsha.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Fatemieh Hospital

**Full name of responsible person**

Dr Mahnaz Yavangi

**Position**

Obstetrician

**Other areas of specialty/work**

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**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*