Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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
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Person responsible for scientific inquiries

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Web page address

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