

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of anti-müllerian hormone levels as a predictive factor of response to weight loss treatment in obese infertile women with PCOS.

Protocol summary

Summary

This study is a prospective before & after clinical trial to compare the basal and 3 months after diet anti-müllerian hormone levels between responders and non-responders to weight loss diet in obese infertile women with PCOS population. The study population comprised of all obese infertile PCOS patients aged 20-40 years which underwent 3 months weight loss diet in Royan institute, Tehran Iran. The study is conducted over 12 wk energy restriction. All subjects have the same dietary protocol. At baseline and 12 wks after the diet, the levels of AMH, FSH, LH, PRL, androgens, sex hormone-binding globulin (SHBG), glucose, and insulin are measured and free androgen index (FAI) and insulin resistance (IR) indices are calculated. The laboratory tests are determined by radioimmunoassays in the laboratory of endocrinology of Royan institute. AMH was measured in duplicate using an ultrasensitive ELISA kit (AMH-EIA; Beckman Coulter, Marseilles, France) according to manufacturer instructions. Patients based on response to diet and improvement are divided two groups) responder and non-responder (.Data analysis will be done through descriptive and perceptive statistical methods by using SPSS software version 16 for windows. Also, if the ART cycle is started for treatment of infertility, the cycle outcomes and pregnancy rate will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302241141N14**

Registration date: **2013-07-06, 1392/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-06, 1392/04/15

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 7960

Email address

kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Royan institute

Expected recruitment start date

2012-10-21, 1391/07/30

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of anti-müllerian hormone levels as a predictive factor of response to weight loss treatment in obese infertile women with PCOS.

Public title

Evaluation blood level of anti-müllerian hormone measurement efficiency in prediction of the response to weight loss diet in obese women with polycystic ovarian syndrome with infertility problem.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: 1-Diagnosis of PCOS, according to the Rotterdam Consensus Workshop Group, by 2 of the following 3 criteria: •Menstrual irregularity (cycle length<26 d or >31 d or variation between consecutive cycles of >3 d); •Clinical (hirsutism assessed by a Ferriman-Gallwey score > 8) or biochemical [free androgen index (FAI) > 5.4 or testosterone_1.4 nmol/L] hyperandrogenism; •Positive ultrasound presentation of polycystic ovaries by transvaginal scan (More than 12 follicles 9-2 mm and increased ovarian volume greater than 10 cm3) . 2-Age between 18 -40 years old. Exclusion criteria: 1.Body mass index (BMI; in kg/m2) < 30. 2.Type 2 diabetes mellitus. 3. Related endocrine disorders [identified by assessment of thyroid-stimulating hormone (TSH), prolactin, and 17_hydroxyprogesterone]. 4.The use of medications affecting the hypothalamus - pituitary - ovarian axis and insulin-sensitizing agents (metformin) is not permitted during the study phase and 12 wk before commencement of the study phase. Also, the use of oral contraceptives is not permitted during and 4 wk before commencement of the study phase. 5.Cases of alcoholism and smoking. 6.Regular exercise activities during the study.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Royan Institute

Street address
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat highway

City
Tehran

Postal code

Approval date
2012-09-25, 1391/07/04

Ethics committee reference number
91/ec/1066

Health conditions studied

1

Description of health condition studied

Obesity in polycystic ovary syndrome women

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
AMH serum level

Timepoint
Before and 12 weeks after starting the diet

Method of measurement
Laboratory (ELISA method)

Secondary outcomes

1

Description
FSH serum level

Timepoint
Before and 12 weeks after starting the diet

Method of measurement
Laboratory kits

2

Description
LH serum level

Timepoint
Before and 12 weeks after starting the diet

Method of measurement
Laboratory kits

3

Description
PRL serum level

Timepoint
Before and 12 weeks after starting the diet

Method of measurement
Laboratory kits

4

Description

androgens serum level
Timepoint
Before and 12 weeks after starting the diet
Method of measurement
Laboratory kits

5

Description
sex hormone-binding globulin (SHBG) serum level
Timepoint
Before and 12 weeks after e starting the diet
Method of measurement
Laboratory kits

6

Description
Free Androgen Index serum level (FAI)
Timepoint
Before and 12 weeks after starting the diet
Method of measurement
Laboratory kits

7

Description
Insulin Resistance (IR) indices
Timepoint
Before and 12 weeks after starting the diet
Method of measurement
Laboratory kits

8

Description
Fasting insulin
Timepoint
Before and 12 weeks after starting the diet
Method of measurement
Laboratory kits

Intervention groups

1

Description
Intervention group:weight loss diet for 12 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Arezo Arabipoor
Street address
Royan Institute, Number 12, East Hafez Avenue, Bani

Hashem Street, Resalat high way, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Royan institute
Full name of responsible person
Dr Vosough
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Royan Institute, Number 12, East Hafez Avenue, Bani
Hashem Street, Resalat high way, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Royan institute
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
Royan institute
Full name of responsible person
Arezo Arabipoor
Position
MS of midwifery/ principal investigator
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Person responsible for scientific inquiries

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Position

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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