Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study the effect of Dehydroepiandrosterone on the ovarian reserve rates and serum anti-Mullerian hormone levels in infertile women with diminished ovarian reserve.

Protocol summary

Summary

Objective: To assess the effect of Dehydroepiandrosterone (DHEA) on ovarian reserve including serum anti-Müllerian hormone (AMH) levels in infertile women with diminished ovarian reserve. Study design: Randomized, not blind, double center, phase 2. Setting and conduct: seventy infertile women with diminished ovarian reserve divided in two groups of 35 based on randomized number table. Patients and physician became aware and informed from intervention. Inclusion criteria: Women aged 20 to 45 years; normal hysterosalpingography; AMH levels < 1.5 ng/ml; antral follicular counts (AFC) < 7 in both ovaries; prior less than three failed in vitro fertilization cycles. Exclusion criteria: Normal ovarian response in ovulatory cycles or in vitro fertilization cycles. Sample size: 70 Intervention: Pretreatment with DHEA supplementation. Intervention time: Six weeks prior to in vitro fertilization cycles. Primary outcome (s): AMH levels changes; Clinical pregnancy rates. Secondary outcome(s): Miscarriage rates, antral follicular counts changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091529374N1**
Registration date: **2017-09-15, 1396/06/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

Name
Marzieh Zamaniyan
Name of organization / entity
Mazandaran University of Medical Sciences, Sari, Iran.
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Science.

Expected recruitment start date

2017-05-27, 1396/03/06

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Dehydroepiandrosterone on the ovarian reserve rates and serum anti-Mullerian hormone levels in infertile women with diminished ovarian reserve.

Public title

Effects of Dehydroepiandrosterone on ovary.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women aged 20 to 45 years; normal hysterosalpingography; AMH levels < 1.5 ng/ml;

antral follicular counts (AFC) < 7 in both ovaries; prior less than three failed in vitro fertilization cycles.
Exclusion criteria: Normal ovarian response in ovulatory cycles or in vitro fertilization cycles.

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Science.

Street address
240 Plaque, Third floor, Mazandaran University of Medical Sciences, Joybar street, Sari, Iran

City
Sari

Postal code
4815659769

Approval date
2017-05-27, 1396/03/06

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.96.2806

Health conditions studied

1

Description of health condition studied
Diseases of the genitourinary system

ICD-10 code
N97; N98

ICD-10 code description
Female infertility; Complications associated with artificial fertilization

Primary outcomes

1

Description
Anti-mullerian hormone rate

Timepoint
Before intervention, six weeks after intervention

Method of measurement
Laboratory kits

2

Description
Clinical pregnancy rates

Timepoint
Forth weeks after embryo transfer

Method of measurement
Questionnare

Secondary outcomes

1

Description
Miscarriage rates

Timepoint
Till twenty weeks after embryo transfer

Method of measurement
File

2

Description
Antral Follicular counts

Timepoint
Before treatment, six weeks after treatments

Method of measurement
ultrasonography

Intervention groups

1

Description
Intervention group: Use of Dehydroepiandrosterone tablet, 25 mg three times a day till 6 weeks.

Category
Treatment - Drugs

2

Description
Control group: No treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility Center, Imam Khomeini Hospital
Full name of responsible person
Marzieh Zamaniyan
Street address
233 plaque, Ground Floor, IVF ward, Imam Khomeini Hospital, Amir Mazandarani Ave, Sari.
City
Sari

2

Recruitment center
Name of recruitment center
Mother Infertility Center
Full name of responsible person
Marzieh Zamaniyan
Street address
345 Plaque, Mother Infertility Clinic, Ground floor, Shahriar 3 Department, Farhang Street, Sari.
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Mazandaran University of Medical Science.
Full name of responsible person
Bahar Farshidfar
Street address
242 Plaque, Third floor, Mazandaran University of Medical Sciences, Joybar street, Sari.
City
Sari
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Mazandaran University of Medical Science.
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
Infertility Center, Department of Obstetrics and Gynecology, Mazandaran University of Medical Scienc
Full name of responsible person
Marzieh Zamaniyan
Position
Assistant professor, M.D.
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Person responsible for updating data

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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