

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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.

Country

Iran (Islamic Republic of)

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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

Questionnaire

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

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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

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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 Science

Full name of responsible person

Marzieh Zamaniyan

Position

Assistant professor, M.D.

Other areas of specialty/work**Street address**

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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