Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect Dehydroepiandrosterone (DHEA) supplementation on IVF outcome

Protocol summary

Study aim
The effect Dehydroepiandrosterone (DHEA) supplementation on IVF outcome
Design
A randomized clinical trial with parallel control group, double blind; Phase 2-3, on 70 patients; randomization is performed by using block randomization
Settings and conduct
Double-blind clinical trial in Fatemieh Hospital, Hamadan
Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidates for IVF over 35 years,Body mass index between 18 and 25(kg/m^2),FSH hormone levels less than 10 IU / L Exclusion criteria: Systemic diseases such as diabetes, thyroid diseases, History of ovarian surgery,History of receiving DHEA
Intervention groups
Taking dihydroepiandrosterone tablets, 25 mg three times a day for 8 weeks and in the control group, the same amount and duration of placebo are given.
Main outcome variables
Primary variables include clinical and chemical pregnancy rate, abortion rate, endometrial thickness and duration of ovarian stimulation.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160523028008N14**
Registration date: **2021-04-05, 1400/01/16**
Registration timing: **prospective**

Last update: **2021-04-05, 1400/01/16**
Update count: **0**
Registration date
2021-04-05, 1400/01/16

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-05-21, 1400/02/31
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect Dehydroepiandrosterone (DHEA) supplementation on IVF outcome

Public title
The effect Dehydroepiandrosterone (DHEA) supplementation on IVF outcome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for IVF over 35 years Body mass index between 18 and 25 (kg/m^2) FSH hormone levels less than 10 IU / L
Exclusion criteria:

Systemic diseases such as diabetes, thyroid diseases History of ovarian surgery History of receiving DHEA

Age

From **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the fact that the drug and placebo are indistinguishable in terms of shape and appearance, patients and the examining physician will not be aware of the type of drug treatment of the patient, so the study will be performed in a double-blind manner.

Placebo

Used

Assignment

Parallel

Other design features

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

Hamdan

Province

Hamadan

Postal code

6517838695

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.UMSHA.REC.1399.1036

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

Fourth week after intervention

Method of measurement

Based on Beta-HCG and ultrasound confirmation

2

Description

Chemical pregnancy rate

Timepoint

The second week after the intervention

Method of measurement

Based on Beta-HCG a confirmation

3

Description

Miscarriage rates

Timepoint

Before 6 and 20 weeks after the intervention

Method of measurement

File

4

Description

Endometrial thickness before embryo transfer

Timepoint

Before embryo transfer

Method of measurement

Using ultrasound

5

Description

Duration of stimulation

Timepoint

Time required for follicle growth

Method of measurement
Using ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Dehydroepiandrosterone pharmaceutical tablet manufacturing company Puritant`pride USA, 25 mg orally three times in 8 weeks before embryo transfer in patients undergoing IVF are given
Category
Treatment - Drugs

2

Description
Control group: Administration of placebo (starch tablets) three times a day for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Soghra Rabiei
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Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Soghra Rabiei
Position
Professor,
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Position
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Latest degree
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Person responsible for updating data

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Gynecology Assistant

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Medical doctor

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information"

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available