# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
**Name**
Mohammad Faryadras
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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**
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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**
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Professor,
**Latest degree**
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## Person responsible for updating data

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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