# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluation of the effect of krocina supplement on the follicular oxidative stress and quality of oocyte and embryo in patients with Diminished ovarian reserve (DOR)

## Protocol summary

**Study aim**

Use of Drug Supplements in the Treatment of Patients Decreased Ovarian Reserve as a Supplement to Ovulation Stimulation Hormone Therapy with Less Complications and More Effective Treatments

**Design**

Clinical trial with control group, with factorial groups, phase 3-2 on 30 patients

**Settings and conduct**

A treatment group consisted of 15 patients with reduced ovarian reserve (based on inclusion and exclusion criteria) three months after taking one crocin pill per day and a control group consisted of 15 patients with reduced ovarian reserve referred to Taleghani Hospital Infertility Center They enter the ovulation stimulation cycle

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: History of uterine bleeding and amenorrhea before 40 years <FSH 10U / L and AMH <0.5 - 1.1 ng / ml. Infertility without a specific cause Exclusion criteria: POI patients with 25 40 IU / ml POF patients with a 4-month period of amenorrhea and <FSH40 Chromosomal disease in each pair Hysterosalpingography, which shows a defective female reproductive system Genetic disorders such as Turner syndrome Patients using alkylating agents or radiation therapy Decreased PTH and aldosterone Patients with hyper or hypothyroidism Type I diabetic patients s

**Intervention groups**

The first group (treatment) :Women with reduced ovarian reserve treated with Crocina supplementation who enter the ovulation stimulation cycle after three months of supplementation.The second group (control): Women with reduced ovarian reserve who enter the ovulation stimulation cycle

**Main outcome variables**

Use of drug supplements in the treatment of patients with DOR with fewer complications and more effective treatments

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220516054872N1**
Registration date: **2022-06-13, 1401/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-13, 1401/03/23**
Update count: **0**

**Registration date**

2022-06-13, 1401/03/23

**Registrant information**

**Name**

Bahareh Karimi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 3522 0008

**Email address**

karimi.b1367@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-01-21, 1400/11/01

**Expected recruitment end date**

2022-10-23, 1401/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of krocina supplement on the follicular oxidative stress and quality of oocyte and embryo in patients with Diminished ovarian reserve (DOR)

**Public title**

Evaluation of the effect of krocina in patients with Diminished ovarian reserve

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

History of uterine bleeding and amenorrhea before 40 years FSH <10U/L و AMH<0.5 – 1.1 ng/ml Infertility without a specific cause

**Exclusion criteria:**

POI patients with 25 40 IU / ml POI patients with 25 40 IU / mlPOF patients with a 4-month period of amenorrhea and <FSH40 Chromosomal disease in each pair Hysterosalpingography, which shows a defective female reproductive system Genetic disorders such as Turner syndrome Patients using alkylating agents or radiation therapy Decreased PTH and aldosterone Patients with hyper or hypothyroidismType I diabetic patients Patients with Cushing's disease or Addison's disease Cases of obesity History of malignant tumor Taking antioxidant-related medications in the last 3 months Use hormone therapy to induce ovulation in the last 2 months History of taking contraceptives in the last 3 months

**Age**

To **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Shahid Beheshti University of Medical Sciences

**Street address**

Arabi Street, Taleghani Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1985711151

**Approval date**

2022-05-23, 1401/03/02

**Ethics committee reference number**

IR.SBMU.MSP.REC.1400.836

## Health conditions studied

**1**

**Description of health condition studied**

Diminished ovarian reserve

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**

patients with Diminished ovarian reserve

**Timepoint**

Measurement of blood FSH, LH and estradiol levels 3 months after taking the drug

**Method of measurement**

Evaluation of number and quality of oocytes extracted from ovarian stimulation using stereomicroscope, measurement of superoxide desmutase level in follicular fluid by spectrophotometry using SOD Assay Kit, detection of reactive oxygen species in granulosa cells using flow cytometry On DCFH-DA, assay of NRF2 gene expression as a marker of oxidative stress suppression and GDF9 and BMP15 genes as marker of oocyte maturation in granulosa cells by qRT-PCR

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: A treatment group consisting of 15 patients with reduced ovarian reserve (based on inclusion and exclusion criteria) received a dose of one Krocina tablet from Sami Pharmacy with a dose of 15 mg

of crocin extract per day for three months and a control group consisted of 15 patients with Decreased ovarian reserve

**Category**
Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Taleqani Hospital

**Full name of responsible person**
Dr. Hamid nazarian

**Street address**
Shahid Chamran Highway, Yemen St., Shahid Arabi St., next to Shahid Beheshti University of Medical Sciences, Ayatollah Taleghani Hospital

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Dr. Hamid nazarian

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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**
Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Dr. Hamid nazarian

**Position**
Associate professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Reproductive Biology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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Bahareh karimi

**Position**
student

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Ph.D.

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available