

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of royal jelly compared with placebo on ovum and embryo quality in infertile women with low ovarian reserve treated by IVF

Protocol summary

2021-10-26, 1400/08/04

Study aim

Determining the effect of royal jelly on ovum and embryo quality in infertile women with low ovarian reserve treated with IVF

Design

Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct

The study population is infertile women with low ovarian reserve treated by IVF in Hazrat Zahra Infertility Center in Shahrekord in 1400

Participants/Inclusion and exclusion criteria

Infertile women with low ovarian reserve under the age of 40 who are candidates for IVF without any underlying disease, history of abdominal and pelvic surgery, male infertility, hysterosalpingography and abnormal prolactin

Intervention groups

In this study, infertile women with low ovarian reserve are candidates for IVF after baseline tests. The intervention group will receive 1 g of Royal Jelly daily for 2 months before the IVF cycle and the control group will receive a placebo

Main outcome variables

The rate of chemical and clinical pregnancies in the study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211024052858N1**

Registration date: **2021-10-26, 1400/08/04**

Registration timing: **prospective**

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

Registrant information

Name

Afroz Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 5505

Email address

afroozjfr@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of royal jelly compared with placebo on ovum and embryo quality in infertile women with low ovarian reserve treated by IVF

Public title

The effect of royal jelly on ovum and embryo quality in infertile women with low ovarian reserve treated by IVF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women with low ovarian reserve under the age of 40 who are candidates for IVF Evaluation of sperm test

and normal hysterosalpingogram Absence of any underlying disease, history of abdominal and pelvic surgery, male infertility, hysterosalpingography and abnormal prolactin Patient consent to participate in the study and collaborate in the follow-up course

Exclusion criteria:

The patient refuses to perform IVF The presence of any underlying disease, history of abdominal and pelvic surgery, male infertility, hysterosalpingography and abnormal prolactin and sensitivity to royal jelly cause the patient to be removed from the examination process

Age

To **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization to two groups of 55 people using a Randomizer software

Blinding (investigator's opinion)

Double blinded

Blinding description

Royal Jelly and placebo capsules will be prepared in the form of capsules and packaging exactly the same as the letters A and B, and the participant and the researcher do not know what capsule A or B contains

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Building No. 2, University Headquarters, Kashani Blvd.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2021-09-28, 1400/07/06

Ethics committee reference number

IR.SKUMS.REC.1400.147

Health conditions studied

1

Description of health condition studied

Infertility with low ovarian reserve

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

The effect of royal jelly on ovum and embryo quality in infertile women with low ovarian reserve treated with IVF

Timepoint

3-5 days after fertilization

Method of measurement

Inner cell mass grading system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Royal Jelly Capsules 1 g daily for 2 months before IVF-ICSI cycle

Category

Treatment - Drugs

2

Description

Control group: Placebo capsules in the same color, shape and size as the intervention capsule

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hazrat Zahra Infertility Center

Full name of responsible person

Maryam Nemati Dehkordi

Street address

West Saadi St., next to Imam Hassan Mosque

City
Shahrekord
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Chahar-Mahal-va-Bakhtiari
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8816866659
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nemati.m@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghi
Street address
Vice Chancellor for Research, Building No. 2,
University Headquarters, Ayatollah Kashani Blvd.
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Sadeghi@skums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Afrooz Jafari
Position
Resident
Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Hajar hospital, Parastar st.

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Maryam Nemati Dehkordi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Afrooz Jafari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Email

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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

Information is kept confidential

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

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

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared

When the data will become available and for how long

After publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Shahrekord University of Medical Sciences, Dr. Maryam Nemati

What processes are involved for a request to access data/document

By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided

Comments