Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Royal Jelly on Sperm Parameters and Functional Tests in Infertile Men with Increased Sperm DNA Damage

Protocol summary

Study aim
Effect of Royal Jelly on Sperm Parameters and Sperm Functional Tests in Infertile Men with Increased Sperm DNA Fragmentation

Design
This study will be conducted on 12–18 infertile individuals with high sperm DNA damage. Participants will receive 1 g of royal jelly daily for 2 months, and sperm parameters, DNA damage, chromatin integrity, and oxidative stress will be evaluated before and after the intervention.

Settings and conduct
This before-and-after clinical trial investigates the effect of royal jelly on infertility in men with high sperm DNA damage. Written informed consent will be obtained from 12–18 participants who provide their sperm samples from the Shahrak Salamat Fertility Center.

Participants/Inclusion and exclusion criteria
The study included infertile men aged 35–55 years with primary infertility and high sperm DNA damage (SCSA > 20%), excluding azoospermic men and those with secondary infertility or lower DNA damage levels.

Intervention groups
Royal jelly, 1 g/day for 2 months (intervention group)

Main outcome variables
Sperm DNA integrity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110804007223N13**
Registration date: **2026-06-15, 1405/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-15, 1405/03/25**
Update count: **0**

Registration date
2026-06-15, 1405/03/25

Registrant information
Name
Mohammad Hossein Nasr-Esfahani
Name of organization / entity
Royan Institute (Royan Institute for Biotechnology)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-10, 1405/03/20

Expected recruitment end date
2026-09-11, 1405/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Royal Jelly on Sperm Parameters and Functional Tests in Infertile Men with Increased Sperm DNA Damage

Public title
Effect of Royal Jelly on Sperm Function

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infertile Men with Sperm DNA Damage Over 20%
Exclusion criteria:

Azoospermic Men Infertile Men with Less Than 20% Sperm DNA Damage

Age
From **35 years** old to **55 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **3**
Semen

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Before-and-After Clinical Trial: In this study, variables in infertile men with high sperm DNA damage were examined before and after treatment with royal jelly.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee at the Royan Institute

Street address
No. 12, Hafez St., Banihashem St., Resalat St., Tehran, Iran

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Province
Tehran

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8165131378

Approval date
2025-03-16, 1403/12/26

Ethics committee reference number
IR.ACECR.ROYAN.REC.1403.103

Health conditions studied

1

Description of health condition studied
Male infertility

ICD-10 code
N-46

ICD-10 code description
Diseases of male genital organs

Primary outcomes

1

Description
Sperm DNA integrity

Timepoint
Before and after using royal gelly dragee

Method of measurement
Flow cytometry

Secondary outcomes

1

Description
Sperm parameters (viability, concentration, motility, morphology)

Timepoint
Before and after useing royal jel dragee

Method of measurement
Computer-Assisted Semen Analysis

2

Description
Protamine deficiency

Timepoint
Before and after useing royal jel dragee

Method of measurement
Fluorescent microscope

3

Description
Lipid peroxidation

Timepoint
Before and after useing royal jel dragee

Method of measurement
flow cytometry

4

Description
Intracellular ROS

Timepoint
Before and after useing royal jel dragee

Method of measurement
flow cytometry

Intervention groups

1

Description
All participants received royal jelly tablets at a daily dose of 1 g for 60 days. The tablets were manufactured by the

Knowledge-Based Honey Jar Company.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Pooyesh Infertility Treatment Center

Full name of responsible person
Mohammad Hossein Nasr-Esfahani

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No. 12, Hafez St., Banihashem St., Resalat St., Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Royan Institute for Biotechnology

Full name of responsible person
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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
Royan Institute for Biotechnology

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Royan Institute for Biotechnology

Full name of responsible person
Mohammad Hossein Nasr-Esfahani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Embryology

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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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

Title and more details about the data/document
After receiving and recording the data,the results can be shared

When the data will become available and for how long
The time of document publication will be after the publication of the manuscript.

To whom data/document is available
Principle investigator

Under which criteria data/document could be used
Only data that has been statistically analyzed can be used.The results of the data are probably applicabe to research and treatment.

From where data/document is obtainable
Mohammad Hossein Nasr Esfahani, Pooyesh Isfahan Infertility Treatment Center

What processes are involved for a request to access data/document
Referring the Pooyesh Esfahan Infertility Treatment Center and asking from Dr. Nasr Esfahani

Comments