Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The impact of 100mg Royal Jelly capsules on the infertility among men

Protocol summary

Study aim
Effects of Royal Jelly on men infertility

Design
Clinical trial on 80 patients with control, parallel, double-blind, and randomized groups, phase 2-3. Permutation block was used to separate people into two groups: intervention and control (4 blocks)

Settings and conduct
The present study, which is a double-blind randomized controlled clinical trial, will be conducted on 80 infertile individuals referred to Sabzevar Vasei urology clinic. The participants will give their informed consent and will be screened and included after meeting the study's inclusion and exclusion criteria. The individuals will be divided into control and intervention groups using a random permutation block as a sampling method. Royal Jelly capsules are taken once a day with standard treatment in the intervention group, while standard treatment is given exclusively in the control group. The Semen test is conducted by the project participants before the intervention, four weeks and eight weeks after the intervention

Participants/Inclusion and exclusion criteria
Requirements for entry: Men aged 20-40 years who have idiopathic infertility, according to WHO criteria; Men aged 20-45, who have been at least 5 years since they decided to have a child and do not use contraception
Requirements for non-entry: Conditions affecting sperm

Intervention groups
Royal Jelly capsules are taken in the intervention group in addition to normal care, which involves taking Pearl Vitamin E 400 and Selenium 200 tablets once a day The control group received normal treatment, which consists daily administration of Pearl Vitamin E 400 and Selenium Pills 200

Main outcome variables
Determining the Royal Jelly’s protective effect on sperm morphology, the sperm count, the sperm viability

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200707048034N1**
Registration date: **2021-09-24, 1400/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-24, 1400/07/02**
Update count: **0**

Registration date
2021-09-24, 1400/07/02

Registrant information
Name
Roya Bagheri
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 4466 0395
Email address
bagheriroya1376@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-23, 1400/07/01
Expected recruitment end date
2021-11-22, 1400/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The impact of 100mg Royal Jelly capsules on the

infertility among men

Public title
The effects of Royal Jelly on male infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men aged 20-45 years who have idiopathic infertility, according to WHO criteria Men aged 20-45, who they have been at least 5 years since they decided to have a child and do not use contraception
Exclusion criteria:
Disorders of the pituitary gland or the hypothalamus Closure of the epididymal duct Testicular and ductal inflammation Alcohol consumption Diabetes
Age
From **20 years** old to **45 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The qualified clients of the urology clinic of Vasei Hospital are sampled using simple random sampling, and after the sampling, they are randomly divided into two groups, namely the control group and the intervention group. In the present study, the subjects are divided into two groups (each group including 40 people) using permuted block technique. In this method, A represents the person who receives intervention and B represents the person who is placed in the control group. Considering the blocks of size 4; code 0 is allocated to permutation AABB, code 1 is allocated to the permutation ABAB, code 2 is allocated to permutation ABBA, code 3 is allocated to permutation BAAB, code 4 is allocated to permutation BBAA, and code 5 is allocated to permutation BABA. Then, a starting point is selected randomly using a random number table. Considering the order of table numbers, we place the relevant permutation of any number we come across
Blinding (investigator's opinion)
Double blinded
Blinding description
This clinical trial is double-blind, indicating that each participant will be allocated codes A and B, and the types of groups will be known only to the researcher, while the participants and treating physician will be uninformed of them
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, above the Memorial of the Shohadaye Gomnam, Shohadaye Hastei Boulevard, Sabzevar, Khorasan Razavi, Iran
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Approval date
2020-04-19, 1399/01/31
Ethics committee reference number
IR.MEDSAB.REC.1399.028

Health conditions studied

1

Description of health condition studied
Male infertility
ICD-10 code
N46
ICD-10 code description
Male infertility

Primary outcomes

1

Description
Semen analysis
Timepoint
Semen analysis prior to intervention, 4 weeks after the intervention, and 8 weeks after intervention
Method of measurement
Semen analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Royal Jelly capsules are taken in the intervention group in addition to normal care, which involves taking Pearl Vitamin E 400 and Selenium 200

tablets once a day

Category

Treatment - Drugs

2

Description

Control group: The control group received normal treatment, which consists of daily administration of Pearl Vitamin E 400 and Selenium Pills 200

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Hamidreza Baghani

Street address

Special Urology Clinic, Vasei Hospital, Tohidshahr Boulevard, Sabzevar, Khorasan Razavi, Iran

City

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Email

vasei.h@medsab.ac.ir

Web page address

https://www.medsab.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Sabzevar University of Medical Sciences' Vice Chancellor for Research and Technology

Street address

Sabzevar University of Medical Sciences, above the Memorial of the Shohadaye Gomnam, Shohadaye Hastei Boulevard, Sabzevar, Khorasan Razavi, Iran

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Web page address

https://www.vcResearch.medsab.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Roya Bagheri

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamidreza Baghani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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Position

Med student

Latest degree

A Level or less

Other areas of specialty/work

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 more information.

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