Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of Royal Jelly on sperm parameters and Testosterone serum level of infertile men

Protocol summary

Study aim
Determining the effect of royal jelly on sperm parameters and testosterone levels in infertile men

Design
Clinical trial without control group, phase 2 per 100 patients

Settings and conduct
In this study, 100 men referred to the infertility treatment center of Imam Khomeini Hospital in Sari, Iran were studied. For this purpose, patients were first monitored for two months and after a two-month period, spermogram were performed, then for two months, they were treated with royal jelly (100 mg) daily and the parameters of sperm and level Serum testosterone will be re-evaluated after this course of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of male infertility by spermogram by kidney and urinary tract specialist (urologist) Infertility history of more than one year Not addiction to smoking or alcohol Absence mass in the testicle Exclusion criteria: History of varicocele surgery Taking sperm boosters in the last 2 months Having Infectious disease Azospermia Having a hormonal disorder Having a history of allergic reactions to royal jelly

Intervention groups
The intervention group includes infertile men who were first monitored for two months and after a two-month period, they underwent spermogram test, then for two months under treatment with royal jelly (100 mg made by Abaidi factory) daily 1 and sperm parameters and their testosterone levels will be re-evaluated after this treatment period.

Main outcome variables
The effectiveness of Royal Jelly on sperm parameters and testosterone levels in infertile men

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180609040028N2**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date
2020-07-29, 1399/05/08

Registrant information

Name
Noushin Gordani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3245 1660

Email address
n.gordani@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of Royal Jelly on sperm parameters and Testosterone serum level of infertile men

Public title
Evaluation of the effect of royal jelly on sperm parameters
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of male infertility by spermogram by urologist Infertility history more than 1 year Not addiction to smoking or alcohol Absence of mass in Testicles
Exclusion criteria:
History of varicocele surgery Taking sperm-boosting drugs in the last 2 months Having a febrile infectious disease Azospermia Having hormonal disorders History of allergic reactions to royal jelly
Age
No age limit
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Infertility Treatment Center, Imam Khomeini Hospital, Amir Mazandarani Blvd, Sari
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2020-07-11, 1399/04/21
Ethics committee reference number
IR.MAZUMS.REC.1399.443

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
Sperm parameters in spermogram test
Timepoint
2 months before the intervention and 2 months after the intervention
Method of measurement
Spermogram test

2

Description
Testosterone level
Timepoint
2 months before the intervention and 2 months after the intervention
Method of measurement
Chemiluminescence immunoassay (CLIA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infertile men are treated with royal jelly (100 mg made by Abidi factory) once a day for two months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Sepideh Peyvandi

Street address
Infertility Treatment Center, Imam Khomeini Hospital, Amir Mazandarani Blvd, Sari
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Email
dr_peyvandi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
Street address
Infertility Treatment Center, Imam Khomeini Hospital, Amir Mazandarani Blvd, Sari
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Grant name
Mazandaran University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Sepideh Peyvandi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Infertility Treatment Center, Imam Khomeini Hospital, Amir Mazandarani Blvd, Sari
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Position
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Only part of the data such as the original outcome information
When the data will become available and for how long
Access period starts 3 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Other researchers can conduct further studies in this area (by sending a request email) to receive unidentifiable personal data.
From where data/document is obtainable
By sending an email request to the project executor at: dr_peyvandi@yahoo.com
What processes are involved for a request to access data/document
By email and up to 2 week
Comments