

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 11 3336 1700

**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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**Phone**

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**Email**

dr\_peyvandi@yahoo.com

**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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

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**Email**

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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**