

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Investigation of the effect of Royal jelly on sexual function in patients undergoing percutaneous coronary intervention: A randomized, double-blind, placebo-controlled trial

#### Protocol summary

##### Study aim

Determination of effect of Royal jelly on sexual function in patients undergoing percutaneous coronary intervention

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 64 patients to allocate consumption to the subjects will use the randomized block method. The website <http://www.randomization.com> will also be used for randomization.

##### Settings and conduct

Sixty-four patients with ischemic heart disease referred to the rehabilitation clinic of Noor Heart Center in Rasht. patients in two groups of 32 will be subjected to intervention with one capsule containing 1000 mg of royal jelly, and the control group will be given a placebo capsule along with a standard diet. The sampling method will be easy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: cardiac patients undergoing angioplasty in the 3rd phase of cardiac rehabilitation, age range 20 to 70 years, sexual function questionnaire score in men less than 26 and in women less than 23. Exclusion criteria: Symptomatic cardiac patients, candidate for stenting in another vessel, history of urological diseases, history of Viagra drug use, taking antidepressants, change in the patient's disease treatment plan during the study, changing the type of drugs used, effective factors studied, reluctance to continue the study or cause any dissatisfaction regarding the consuming royal jelly or participation in the study, body mass index greater than 35, taking warfarin

##### Intervention groups

Intervention group: cardiac patients undergoing angioplasty in the 3rd phase of cardiac rehabilitation, one capsule containing 1000 mg of royal jelly will be

prescribed daily for 8 weeks. Control group: cardiac patients undergoing angioplasty in the 3rd phase of cardiac rehabilitation, one capsule daily for 8 weeks The number of placebo capsules is prescribed.

##### Main outcome variables

sexual function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038626N13**

Registration date: **2023-11-06, 1402/08/15**

Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**

Update count: **0**

##### Registration date

2023-11-06, 1402/08/15

##### Registrant information

##### Name

Zahra Ahmadnia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3361 8177

##### Email address

zahmadnia@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-03-20, 1403/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of the effect of Royal jelly on sexual function in patients undergoing percutaneous coronary intervention: A randomized, double-blind, placebo-controlled trial

**Public title**

effect of Royal jelly on sexual function in patients undergoing percutaneous coronary intervention

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Cardiac patients undergoing angioplasty in phase 3 of cardiac rehabilitation Married Patients with an age range of 20 to 70 years The score of sexual function questionnaire in men is less than 26 and in women less than 23

**Exclusion criteria:**

Symptomatic cardiac patients Candidate for stenting in another vessel History of urological diseases History of Viagra drug use Taking antidepressants Change in the patient's disease treatment plan during the study Changing the type of drugs used, effective factors studied Reluctance to continue the study or cause any dissatisfaction regarding the consuming royal jelly or participation in the study Body mass index greater than 35 Taking warfarin

**Age**

From **20 years** old to **70 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of sampling and randomization of the two-blind, parallel-group clinical trial study will be stratified block randomization. each person was randomly assigned to the intervention or control group using 1: 4 random blocks. Took. In this method, each group will be assigned one of the letters A or B. The website will also be used for randomization. The list of codes obtained from this website will be provided to the researchers, and each referring patient who met the inclusion criteria and did not meet the inclusion criteria and was willing to participate in the study, first entered the desired age

group and based on The assigned code A or B enters the design. For concealment, in this study, random allocation concealment, which is the method used to execute a random sequence on the study participants, will be used in such a way that the assigned group is not known before the individual is assigned. In this way, using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Since the capsules containing royal jelly and placebo have been tried to be completely similar to each other due to the similarity in taste, taste, aroma and smell, the patients receiving and the researchers providing the supplements are of the type of supplement that each participant receives. They will not be aware.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

**Street address**

Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

41446-66949

**Approval date**

2023-10-18, 1402/07/26

**Ethics committee reference number**

IR.GUMS.REC.1402.389

**Health conditions studied**

## 1

### **Description of health condition studied**

Ischaemic heart diseases

### **ICD-10 code**

I20-I25

### **ICD-10 code description**

Ischaemic heart diseases

## **Primary outcomes**

### 1

#### **Description**

sexual function

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

FSFI questionnaire, IIEF questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Depression

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

13-question short form depression questionnaire

### 2

#### **Description**

Serum lipid profile levels (triglycerides, total cholesterol, LDL-C and HDL-C)

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

BT2000 device

### 3

#### **Description**

Prothrombin Time

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

ELISA device

### 4

#### **Description**

Partial Thromboplastin Time

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

ELISA device

### 5

#### **Description**

Mean systolic and diastolic blood pressure

### **Timepoint**

At the beginning of the study and 8 weeks later

### **Method of measurement**

Pressure indicator

### 6

#### **Description**

Erythrocyte sedimentation rate

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

ELISA device

### 7

#### **Description**

C-reactive protein

#### **Timepoint**

At the beginning of the study and 8 weeks later

#### **Method of measurement**

ELISA device

## **Intervention groups**

### 1

#### **Description**

Intervention group: cardiac patients undergoing angioplasty in the 3rd phase of cardiac rehabilitation, one capsule containing 1000 mg of royal jelly will be prescribed daily for 8 weeks.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: cardiac patients undergoing angioplasty in the 3rd phase of cardiac rehabilitation, one capsule daily for 8 weeks. The number of placebo capsules is prescribed.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Noor specialist heart clinic

##### **Full name of responsible person**

Zahra Ahmadnia

##### **Street address**

Moalem St, Noor specialist heart clinic

##### **City**

Rasht

##### **Province**

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##### **Postal code**

-

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Ramyar Farzan  
**Street address**  
Technology & Research Vice-chancellor of University;  
Shahid Siadati St; Namjoo St., Rasht  
**City**  
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+98 13 3333 5821  
**Email**  
ramyarfarzan@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Rasht 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**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Zahra Ahmadnia  
**Position**  
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**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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