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
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Iran (Islamic Republic of)
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+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
120-125
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
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-

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Position
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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