

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Date Palm Pollen (D.P.P) on sexual desire and potency of male patients after coronary artery bypassgraft surgery

Protocol summary

Study aim

The effect of date palm pollen product on sexual desire and ability of male patients after coronary artery bypass graft surgery

Design

A randomized controlled clinical trial with parallel groups, double blinded

Settings and conduct

The research center is Tehran Heart Center. The drug used is 3 grams of date palm pollen and placebo 3 grams of Avicel powder, both administered every 12 hours for 2 months. Both are similar in appearance and packaging, only distinguishable by proprietary codes inserted on the drug label by the pharmacist. The patient and the prescriber are not aware of the meaning of the codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients undergoing coronary artery bypass surgery; sexual dysfunction; IIEF score less than 50; ejection fraction greater than 30%; male Gender; age: 40 to 70 years old. Exclusion criteria: creatinine over 1.5; AST and ALT are more than twice the normal; history or prostate cancer; CABG again; active inflammatory diseases; myocardial infarction in the past 6 months; CABG with valve replacement; EF less than 30%; uncontrolled thyroid disorders; anemia; pre-surgery sexual dysfunction; major depression; consumption of high dose beta blockers; coldness of marital relations that leads to inability to have sex; history of allergies to pollen of flowers and plants.

Intervention groups

Intervention group: 3 grams of _Shahani Date palm pollen from Jahrom sachet one morning 9 and one night 9, for 8 weeks. Control group: 3 grams of Avisel sachet one morning 9 and one night 9, for 8 weeks.

Main outcome variables

Index of erectile function; index of sexual desire

General information

Reason for update

From the beginning, the study was double-blind, which was mistakenly recorded triple-blind, so this mistake corrected. Due to the fact that symptomatic patients usually have an IIEF below 50, this criterion was modified in consultation with specialists and according to other similar studies. Due to the fact that bypass patients are mainly suffering from metabolic syndrome, including diabetes, it was excluded from the exclusion criteria with the advice of diabetes experts. The sample size was modified for two reasons: first, due to observations of studies that allowed us to complete the work with a smaller sample size, and second, due to COVID19 pandemic non-emergency surgery and follow-up of patients was disrupted. Therefore, in consultation with the statistics consultant and finding supportive studies, the sample size was corrected and the study was terminated and the data were analyzed.

Acronym

DPP

IRCT registration information

IRCT registration number: **IRCT20191228045911N1**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **retrospective**

Last update: **2021-06-13, 1400/03/23**

Update count: **1**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Hamed Hooshang malamiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5590 2078

Email address

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-03, 1398/06/12

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

2019-09-03, 1398/06/12

Actual recruitment end date

2020-02-21, 1398/12/02

Trial completion date

2020-09-21, 1399/06/31

Scientific title

Evaluation of the effect of Date Palm Pollen (D.P.P) on sexual desire and potency of male patients after coronary artery bypassgraft surgery

Public title

The effect of date palm pollen on sexual desire and potency of cardiac patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing coronary artery bypass surgery
Sexual dysfunction IIEF score less than 50 Ejection fraction greater than 30% Male Gender Age : 40 to 70 years old

Exclusion criteria:

Creatinine over 1.5 AST and ALT are more than twice the normal History or Prostate Cancer CABG again Active inflammatory diseases Myocardial infarction in the past 6 months EF less than 30% Uncontrolled thyroid disorders Major depression Coldness of marital relations that leads to inability to have sex. History of allergies to pollen of flowers and plants

Age

From **40 years** old to **70 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients to study groups is done using Block Randomization method. Samples are divided into

intervention and placebo groups based on the random sequence generated by the statistic consultant. A random sequence is generated by random four-way blocks; each block represents four participants. Distribution of placebo and interventions in each block is random but under a condition that there must be two placebos and two interventions in each block. Using this method, the number of samples assigned to each of the groups are equal, so in cases that mid-term analysis is required, the equal number of samples for both groups are available.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication and placebo are identical in terms of appearance an packaging, only differentiated through the proprietary codes set by the pharmacist on the box of medicine. The patient and the prescribing researcher are not aware of the code. The outcomes of the study are prepared by the researcher who is unaware of the grouping and is blind to the groups and type of medications.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor in research affairs- Tehran university of medical Sciences

Street address

Vice Chancellor for Research and Technology, Sixth Floor, Ghods Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-02-10, 1398/11/21

Ethics committee reference number

IR.TUMS.VCR.REC.1398.915

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

2**Description of health condition studied**

Low sexual desire

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

Primary outcomes**1****Description**

Erectile function

Timepoint

Before intervention, week 4 and week 8 after intervention

Method of measurement

International Index of Erectile Function Questionnaire

2**Description**

Sexual desire

Timepoint

Before intervention, week 4 and week 8 after intervention

Method of measurement

Halbert index of sexual desire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 3 grams sachet of Shahani date palm pollen of Jahrom, containing fine Powder of date palm pollen, one in the morning and one in the night, for 8 weeks

Category

Treatment - Drugs

2**Description**

Control group: 3 grams sachet of Avisel containing fine Powder of Avisel, one in the morning and one in the night, for 8 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Heart Center

Full name of responsible person

Hamed Hooshang Malamiri

Street address

Kargar-Shomali street

City

Tehran

Province

Tehran

Postal code

1439957181

Phone

+98 21 8802 9600

Email

hushanghamed@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

Vice Chancellor for Research and Technology, Sixth Floor, Ghods Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hamed Hooshang Malamiri

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

College of Iranian medicine, No. 27 , Shahid

Şarparast-e-shomali street

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8897 6527

Email

mirzahamed69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamed Hooshang Malamiri

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

College of Iranian medicine, No. 27, Shahid Sarparast-

e-Shomali street

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8897 6527

Email

mirzahamed69@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamed Hooshang Malamiri

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

College of Iranian medicine, No. 27, Shahid Sarparast-

e-Shomali

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8897 6527

Email

mirzahamed69@gmail.com

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

Not applicable