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

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Email address

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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
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1439957181
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraeian
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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
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

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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
Not applicable