Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the Antioxidant Role of Palm Pollen in Oligospermic and Asthenozoospermic Men and Its Correlation with Count, Motility and Morphology of the Sperm

Protocol summary

Study aim
The aim of this study was to investigate: The effect of palm pollen on sexual parameters As well as the expression of antioxidant genes Sex hormones in infertile men

Design
single-blind, and comparative clinical trial

Settings and conduct
This study was conducted during 2015. Palm pollen at a dose of 400 mg / kg in gelatin capsules was used for two consecutive months to treat eligible individuals. The control group was selected. Semen samples were analyzed before and after palm pollen treatment in the case group and also semen samples in the control group according to WHO guidelines.

Participants/Inclusion and exclusion criteria
Infertile men aged 20 to 42 years were included in the study We excluded the case with these criteria from the research: history of genetic and systemic disorders, reproductive tract abnormality, testicular trauma, alcohol and substance abuse, and fertility medications at least for six months before participation.

Intervention groups
In order to intervene in the case group, in addition to receiving standard infertility medication by a specialist physician, they also received 400 mg / kg palm pollen powder in gelatin capsules for two months.

Main outcome variables
Changes in sperm parameters Sex hormones and prolactin free 8-Isoprostane Expression of SOD-CAT-NRF2-GPX4 genes

General information

Reason for update
Increase the sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT2015020120895N2**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **prospective**

Last update: **2021-05-03, 1400/02/13**
Update count: **1**

Registration date
2015-10-12, 1394/07/20

Registrant information

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Soghra Fallahi

Name of organization / entity
Hormozgan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Hormozgan University of Medical Sciences

Expected recruitment start date
2016-03-21, 1395/01/02

Expected recruitment end date
2017-09-23, 1396/07/01

Actual recruitment start date
2016-03-12, 1394/12/22

Actual recruitment end date
2017-06-11, 1396/03/21

Trial completion date
2017-06-22, 1396/04/01

Scientific title
Evaluation of the Antioxidant Role of Palm Pollen in Oligospermic and Asthenozoospermic Men and Its Correlation with Count, Motility and Morphology of the Sperm

Public title
Antioxidant role of palm pollen in infertility

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Normal anatomy of the genital area; Infertility due to oligo asthenospermia

Exclusion criteria:
The case with the following criteria were excluded from the study: history of genetic and systemic disorders, reproductive tract abnormality, testicular trauma, alcohol and substance abuse, and fertility medications at least for six months before participation.

Age
From **20 years** old to **42 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **120**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with sealed envelope

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a randomized, single-blind and comparative clinical trial including 60 cases of male infertility that was conducted during the year March to June 17, 2016. Palm pollen powder at a rate of 400 mg / kg in gelatin capsules was used for two consecutive months to treat eligible individuals.Have been received. The coding is done by one of the project partners and they are blind evaluators.

Placebo
Not used

Assignment
Other

Other design features
Participants entered the study after signing a personal and written consent form based on inclusion criteria. Their cement sample was measured before and after treatment with palm pollen capsule for two months in the case group and also the sample of the control group was measured according to the WHO 2010 analysis analysis guidelines. Also, the concentration of 8-Isoprostane, antioxidant genes was examined.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Molecular Medical Research Center of Bandar Abbas University of Medical Sciences

Street address
Kamarbandi St., Jomhuri Eslami Boulevard,Shahid Mohammadi Hospital,Molecular Medicine Laboratory, Bandar Abbas, Iran

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Bandar Abbas

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Approval date
2015-02-23, 1393/12/04

Ethics committee reference number
HEC-93-12-4

Health conditions studied

1

Description of health condition studied
Male infertility

ICD-10 code
N46

ICD-10 code description
Azoospermia NOS Oligospermia NOS

Primary outcomes

1

Description
Evaluation of count, motility and morphology of sperm

Timepoint
2 months

Method of measurement
Semen analysis

2

Description
Evaluation of expression of antioxidant SOD, CAT, GPX, NRF2 and KEAP1 genes

Timepoint
2 months

Method of measurement
RT-PCR

Secondary outcomes

1

Description
Semen samples were obtained twice from the case group, before and after treatment, and once from the control group through masturbation, masturbation and abstinence for three to five days. We then collected fresh semen samples in sterile plastic containers.
Timepoint
2 months after consumption of palm pollen
Method of measurement
The samples were exposed to 37 ° C for 30 minutes for liquefaction and semen analysis (fluid volume, pH, viscosity, sperm morphology, concentration and motility) was performed immediately according to the WHO guideline. Sex hormones were also examined using ELISA. In addition, in this clinical trial, a blind and comparative semen analysis was performed by a technician blindly.

2

Description
Measurement of antioxidant genes and 8- isoprene index
Timepoint
After two months, receive palm pollen
Method of measurement
BSA-free Ham's-F10 was used twice to wash the samples and then stored in RNALater solution (Qiagen: Germany) at -80 ° C until RNA extraction. Then, after extraction and PCR test, real-time test was performed on the samples.

Intervention groups

1

Description
In addition to standard treatment by a urologist, the case group received 400 mg / kg of palm pollen powder in gelatin capsules for two months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Om-e-Leila fertility and infertility Clinic
Full name of responsible person
Dr Soghra Fallahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Bandare-abbas 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
fertility and infertility Research Center of Shahid Mohammadi Hospital, Bandar Abbas, Iran
Full name of responsible person
Dr Soghra Fallahi
Position
PhD Student Research of Reproductive biology

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Abstract and original article after publication
When the data will become available and for how long
two months
To whom data/document is available
researchers
Under which criteria data/document could be used
To conduct scientific research
From where data/document is obtainable
To the clinical trial site
What processes are involved for a request to access data/document
Email - Call - SMS
Comments
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