Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Date Palm Pollen on the expression of PRDX1 and PRDX6 antioxidant genes in infertile men

Protocol summary

Study aim
The aim of this study: The Evaluation of Date Palm Pollen effect on sexual parameters As well as the expression of antioxidant genes and 8-isoprostane index of Sex hormones in infertile Men

Design
single-blind and comparative clinical trial

Settings and conduct
This study was conducted during 2015. Date Palm Pollen at a dose of 400 mg/ kg in gelatin capsules was used for 74 consecutive days to treat eligible individuals.Ten fertile men was selected as control group. Semen samples were analyzed before and after Date Palm Pollen treatment in the case group and also semen samples were analyzed in the control group according to WHO guidelines. furthermore, the free 8-isoprostane levels and PRDX1 and PRDX6 antioxidant genes expression were evaluated.

Participants/Inclusion and exclusion criteria
Infertile men aged 20 to 45 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 74 days.

Main outcome variables
Changes in sperm parameters of Sex hormones, free 8-Isoprostane levels and expression of PRDX1 and PRDX6 genes

General information

Reason for update
Increase the sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT2015021221014N2**
Registration date: **2015-12-29, 1394/10/08**
Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**
Update count: **1**

Registration date
2015-12-29, 1394/10/08

Registrant information

Name
Kianoosh Malekzadeh
Name of organization / entity
Hormozgan university of medical science
Country
Iran (Islamic Republic of)
Phone
+98 76 3335 4939
Email address
kianoosh.malekzadeh@hums.ac.ir

Recruitment status
Recruitment complete

Funding source
Governmental

Expected recruitment start date
2016-03-27, 1395/01/08

Expected recruitment end date
2017-10-04, 1396/07/12

Actual recruitment start date
2016-03-18, 1394/12/28

Actual recruitment end date
2017-06-19, 1396/03/29

Trial completion date
2017-07-23, 1396/05/01

Scientific title
Evaluation of Date Palm Pollen on the expression of

PRDX1 and PRDX6 antioxidant genes in infertile men

Public title
The study of Date Palm Pollen effect on sperm parameters in infertile men
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 **45 years** old
Gender
Male

Phase
2
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with sealed envelope
Blinding (investigator's opinion)
Single blinded
Blinding description
.The patien Have been received medicine in sealed encoded envelopes. The coding is done by one of the project partners and they are blind evaluators.
Placebo
Not used
Assignment
Parallel
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 Date Palm Pollen capsule for 74 days 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
City
Bandar abbas
Province
Hormozgan
Postal code
7915915517
Approval date
2015-03-16, 1393/12/25
Ethics committee reference number
IR.HUMS.REC.1394.201

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
Change in count, Motility and morphology of sperm
Timepoint
74 days after intervention
Method of measurement
Semen analysis

2

Description
change in PRDX1,PRDX6 antioxidant gene expression
Timepoint
74 days after intervention
Method of measurement
evaluation of gene expression using Real time PCR Method.

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

74 days after consumption of Date 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.

Intervention groups

1

Description

In addition to standard treatment by a urologist, the case group received 400 mg / kg of Date palm pollen powder in gelatin capsules for 74 days.

Category

Treatment - Drugs

2

Description

Intervention Control: Vitamin E 400 unit per day; L-Carnitine daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Om-e-Leila fertility and infertility Clinic

Full name of responsible person

Kianoosh malekzadeh

Street address

Enghelab St, Om-e-Leila Hospital,Fertility and infertility Clinic, Bandar Abbas, Iran

City

Bandar abbas

Province

Hormozgan

Postal code

7915868462

Phone

+98 76 3333 7192

Fax

+98 76 3333 7192

Email

Keyanoosh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Kianoosh malekzadeh

Street address

Kamarbandi St., Islamic Republic Boulevard, Shahid Mohammadi Hospital, fertility and Infertility Research Center, Bandar Abbas, Iran

City

Bandar abbas

Province

Hormozgan

Postal code

7915868462

Phone

+98 76 3333 7192

Email

Keyanoosh@gmail.com

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Kianoosh malekzadeh

Position

Faculty of medicine, Hormozgan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

fertility and infertility Research Center of Shahid Mohammadi Hospital, Bandar Abbas, Iran

City

Bandar abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3333 7192

Fax

Email

Keyanoosh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Molecular Medicine Research Center

Full name of responsible person

Kianoosh malekzadeh

Position

Faculty of medicine, Hormozgan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Kamarbandi St., Islamic Republic Boulevard, Shahid Mohammadi Hospital, fertility and Infertility Research Center, Bandar Abbas, Iran

City

Bandar abbas

Province

Hormozgan

Postal code

7915915517

Phone

+98 76 3333 7192

Fax

Email

Keyanoosh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Molecular Medicine Research Center

Full name of responsible person

Alimohammad falahati

Position

Master of science in medical genetic, Hormozgan University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Medical Genetics

Street address

Kamarbandi St., Islamic Republic Boulevard, Shahid Mohammadi Hospital, fertility and Infertility Research Center, Bandar Abbas, Iran

City

Bandar abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3333 7192

Fax

Email

Falahatidiamond@gmail.com

Web page address

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

The study results will be published as an article. The study protocol and statistical analysis used in the article will be considered.

When the data will become available and for how long

It will be published a year after the study is completed and will be available in the sources.

To whom data/document is available

Information will be made available after permission of the sponsor for academic researchers, physicians and academic institutions.

Under which criteria data/document could be used

Other researchers can use the results of the study in their review and meta-analysis.

From where data/document is obtainable

Dr Soghra fallahi, PhD by research, Hormozgan university of medical science

What processes are involved for a request to access data/document

upon request, the corresponding author will respond after consulting with the sponsor of the study

Comments