Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of bee pollen on spermatogram parameters in infertile men

Protocol summary

Study aim
Effect of bee pollen on spermatogram parameters in infertile men

Design
infertile men who refer to clinic, are randomly divided in two groups. control group receive routine infertility therapy drugs by physician and the test group in addition to the routine infertility therapy drugs, receive bee pollen tablets (2 tabs once daily). at the end of study, sperm samples will take from both groups and spermatogram is carried out. sample size was determined (33 each) based on statistical formula for comparing qualitative variables in two independent population.

Settings and conduct
after filling consent form by individuals who refer to clinic, they were randomly divide to two groups. control group receive routine infertility drugs. intervention group receive routine infertility drugs plus bee pollen tablets (2 tabs once daily). on days 0 and 90 sperm samples were taken from both group and spermatogram is carried out. Results of each group including number, mobility and quality of sperms will be compared.

Participants/Inclusion and exclusion criteria
18-65 years old - infertile men who refer to the clinic during 2019-2020 Participants will be rejected from study in cases of sensitivity to bee pollen, varicocele grades 3 and 4, testes atrophy, ejaculation disturbances and azoospermia

Intervention groups
intervention group: receiving bee pollen tablets + routine infertility drugs Control group: receiving routine infertility drugs

Main outcome variables
Number, mobility and quality of sperms in seminal fluid, Concentration of sperm based on number in milliliter. total motility of sperms based on percent of mobile ones and percent of normal sperms.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190112042330N1**
Registration date: **2019-01-18, 1397/10/28**
Registration timing: **prospective**

Last update: **2019-01-18, 1397/10/28**
Update count: **0**

Registration date
2019-01-18, 1397/10/28

Registrant information

Name
Mohammad Taher Boroushaki

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3800 2261

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-01, 1397/12/10

Expected recruitment end date
2020-05-30, 1399/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of bee pollen on spermatogram parameters in

infertile men

Public title
effect of bee pollen on infertility in men
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
infertile men between 18 and 65 years old who refers to clinic in 2019-2020
Exclusion criteria:
sensitivity to bee pollen, varicocele grades 3&4, testes atrophy, ejaculation disturbances, using any drugs during last 2 month and azoospermia patients
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **2**
More than 1 sample in each individual
Number of samples in each individual: **2**
sperm samples
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
only participants, they divided in two group and each group is unaware of drug therapy in other group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee, mashhad University of Medical Sciences
Street address
Azadi Square, Faculty of Medicine, Dept of Pharmacology
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2018-07-18, 1397/04/27
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.228

Health conditions studied

1

Description of health condition studied
Male infertility
ICD-10 code
N46
ICD-10 code description
Male infertility

Primary outcomes

1

Description
increasing in number, motility and quality of sperm in infertile men
Timepoint
on days 0 and 90 spermatogram is carried out
Method of measurement
spermatogram

Secondary outcomes

1

Description
Treatment of infertility
Timepoint
3-6 months after intervention
Method of measurement
Self - report by individual.

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Dept of Pharmacology, faculty of Medicine

Full name of responsible person
Mohammad Taher Boroushaki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mohammad Taher Boroushaki

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
There is no further information
When the data will become available and for how long
At the end of study, data will be published as an article
To whom data/document is available
All researchers who are interested in this field of study including academic and institutional ones
Under which criteria data/document could be used
Accessing to more data, excluding the article, requires the Research Committee of Mashhad University of Medical Sciences permision
From where data/document is obtainable
by sending email to corresponding author
What processes are involved for a request to access data/document
After receiving email, it is refer to Research Committee of MUMS, after getting permission data will be sent to the applicant.
Comments