

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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)

Phone

+98 51 3800 2261

Email address

boroushakimt@mums.ac.ir

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

Mohsen Tafaghodi

Street address

Vice Presidency in Research, MUMS, Daneshgah Ave,

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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 scientific inquiries

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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 permission

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