Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determination of radio protective effect of Royal Jelly on ionizing radiation-induced DNA damage in human peripheral blood lymphocytes

Protocol summary

Summary

The aim of this study is to determine radio protective effect of royal jelly on ionizing radiation-induced DNA damage in human peripheral blood lymphocytes. In this quasi experimental study, men at the age of 20 to 45 year old would attend. All participants with a history of radiotherapy, chemotherapy and allergy to royal jelly would be excluded. 30 men admitted to Hazrat-e-Maryam fertility center would participate in our study. In this study each participant gives blood samples twice. First sampling, on admission to the fertility center. After first sampling each participant would start taking orally 1000 mg royal jelly per day for two weeks. Second sampling would happen after this period. In each sampling step, blood samples would be divided into two parts, pre-irradiated and post-irradiated, and all of them would be investigated regarding DNA damage by Comet Assay. Primary outcome measures are DNA tail length.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090819091N1**
Registration date: **2014-09-13, 1393/06/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-09-13, 1393/06/22

Registrant information

Name

Navid Rafat

Name of organization / entity

Babol university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Bobol university of medical science . Hazrat-e Maryam Fertility Center (Mazandaran, Sari)

Expected recruitment start date

2015-02-04, 1393/11/15

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of radio protective effect of Royal Jelly on ionizing radiation-induced DNA damage in human peripheral blood lymphocytes

Public title

Radio protective effect of royal jelly against ionizing-radiation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: men; at the age of 20 to 45 year old; Exclusion criteria: having a history of cancer; autoimmune diseases; having allergy to bee sting, to honey, to royal jelly and pollen; having a history of smoking; radiotherapy; chemotherapy; nuclear medicine scan; antibiotic therapy during last three months before attending the study.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol university of medical sciences

Street address

Babol university of medical sciences, Ganj afrooz Av, Babol, Mazandaran

City

Babol

Postal code

Approval date

2014-08-16, 1393/05/25

Ethics committee reference number

4447 30/ژ/پ

Health conditions studied

1

Description of health condition studied

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

2

Description of health condition studied

Radiation exposure

ICD-10 code

Z58.4

ICD-10 code description

Exposure to radiation

3

Description of health condition studied

Ionizing radiation exposure

ICD-10 code

W88

ICD-10 code description

Exposure to ionizing radiation

Primary outcomes

1

Description

Lymphocyte DNA tail length

Timepoint

A)On admission B)Two weeks after oral administration of royal jelly

Method of measurement

Visual scoring of DNA tail

Secondary outcomes

1

Description

Sperm count in semen sample

Timepoint

A)On admission B)75 days after oral administration of royal jelly

Method of measurement

Hemocytometer

2

Description

Gamma radiation dose

Timepoint

A)On admission B)75 days after oral administration of royal jelly

Method of measurement

in Gy scale measured by gamma radiation dosimeter

3

Description

Sperm morphology in semen sample

Timepoint

A)On admission B)75 days after oral administration of royal jelly

Method of measurement

Hemocytometer

4

Description

Sperm motility in semen sample

Timepoint

A)On admission B)75 days after oral administration of royal jelly

Method of measurement

Hemocytometer

Intervention groups

1

Description
This is an quasi-experimental study just including intervention group. In this study each participant gives blood samples twice. First sampling, on admission to the fertility center. After first sampling each participant would start taking orally 1000 mg royal jelly per day for two weeks. Second sampling would happen after this two-week period. In each sampling step, blood samples would be divided into two parts,pre-irradiated and post-irradiated, and all of them would be investigated regarding DNA damage by Comet Assay.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat-e Maryam Fertility Center

Full name of responsible person
Dr. Maryam Shahidi(PhD of medical physics,embryologist/Assistant professor)

Street address
Hazrat-e Maryam Fertility Center, Pasdaran Blv, Imam square, Sari, Mazandaran

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol university of medical sciences

Full name of responsible person
Dr. Moghaddam nia

Street address
Babol university of medical sciences, Ganj afrooz Av, Babol, Mazandaran

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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
Babol university of medical sciences

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

2

Sponsor

Name of organization / entity
Hazrat-e Maryam Fertility Center

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
Hazrat-e Maryam Fertility Center

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Babol university of medical sciences

Full name of responsible person
Dr. Ali Shabestani Monfared

Position
PhD of medical physics/Professor at Babol university of medical sciences

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty