Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assesment of radioprotective effect of Grape seed extract against 6 Mev X-ray in human blood lymphocyte by micronuclei assay

Protocol summary

Study aim
The aim of this study to investigate the radioprotective effect of Grape seed extract against genotoxicity induced by 6 MV x-ray irradiation in human blood lymphocytes

Design
Nine volunteers were divided into three group, the first group received 100 mg, the second group received 200mg and the third group received 600mg doses of Grape seed extract. blood samples were collected from volunteers 15 minutes before (control) and 1, 2 and 5 hours after given Grape seed extract, then samples were divided into two group, the one group as the control group(without radiation) and the other one exposed by 2Gy of 6Mv x-ray. finally, chromosomal aberrations will be assessed by micronuclei assay.

Settings and conduct
Healthy volunteers were selected, blood samples were collected from volunteers before and after given grape seed extract, to expose by x-ray samples move to the Omid Hospital of Mashhad, after of radiation and cell cultures, the number of micronuclei that represented chromosomal aberrations will be assessed.

Participants/Inclusion and exclusion criteria
Volunteers no smoker, Age of 20-30 years and did not no history of cancer, chemotherapy, radiotherapy and nuclear medicine

Intervention groups
Nine volunteers were selected, blood samples were collected from volunteers 15 minutes before and 1, 2 and 5 hours after given Grape seed extract, then samples were exposed by 2Gy of 6Mv x-ray.

Main outcome variables
The number of micronuclei

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160204026361N2**
Registration date: **2018-06-21, 1397/03/31**
Registration timing: **prospective**

Last update: **2018-06-21, 1397/03/31**
Update count: **0**

Registration date
2018-06-21, 1397/03/31

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3822 8590

Email address
r-ghasemnezhad@alumnus.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-07-23, 1397/05/01

Actual recruitment start date
2018-06-22, 1397/04/01

Actual recruitment end date
2018-07-23, 1397/05/01

Trial completion date
empty

Scientific title
Assesment of radioprotective effect of Grape seed extract against 6 Mev X-ray in human blood lymphocyte by micronuclei assay

Public title
Radio protective effect of Grape seed extract

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy human volunteer,no smoker No history of pharmacotherapy Did not suffer from any serious acute or chronic diseases Age range from 20 to 30 years Male Sex
Exclusion criteria:
Smoker Under pharmacotherapy Suffer from any serious acute or chronic diseases
Age
From **20 years** old to **30 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **9**
More than 1 sample in each individual
Number of samples in each individual: **4**
15 minute before and 1, 2 and 5 hours after ingestion of Grape seed extract
Actual sample size reached: **9**
More than 1 sample in each individual
Actual sample size in each individual: **4**
15 minute before, and 1, 2, and 5 hours after GSE oral administration
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
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Science, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9138735499
Approval date
2016-05-07, 1395/02/18
Ethics committee reference number
IR. MUMS.REC.1395.68

Health conditions studied

1

Description of health condition studied
Exposure to ionizing radiation
ICD-10 code
W88.0
ICD-10 code description
Exposure to X-rays

Primary outcomes

1

Description
The number of micronuclei
Timepoint
Blood samples were collected 15 minutes before(control group) and 1, 2 and 5 hours after given Grape seed extract.
Method of measurement
Micronucleus assay

Secondary outcomes

empty

Intervention groups

1

Description
Nine volunteers selected then blood samples were collected 15 minutes before(control group) and 1, 2 and 5 hours after given grape seed extract, then exposed by 6Mv x-ray. Finally, chromosomal aberration investigates by micronucleus assay.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Artesh 550 Hospital
Full name of responsible person
Valiallah Saba
Street address
Bahar Ave., Next to Etka Market
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9137913316

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research Of Aja University of Medical Sciences

Full name of responsible person
Valiallah Saba

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West Fatemi Ave

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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
Vice Chancellor for Research Of Aja University of Medical Sciences

Proportion provided by this source
90

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
Reza Ghasemnezhad

Position
MSc of Radiobiology

Latest degree
Master

Other areas of specialty/work
Radiobiology and Radio safety

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Associate Professor of AJA University of Medical Sciences

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Ph.D.

Other areas of specialty/work
Medical Physics

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Person responsible for updating data

Contact

Name of organization / entity
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Reza Ghasemnezhad

Position
Msc of Radiobiology

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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
No more information
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
No - There is not 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