Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assesment of radioprotector effect of Selenium and Vitamin E synergically againt 6Mv X-ray in human blood lymphocyte by micronucli assay.

Protocol summary

Summary
The aim of this study will evaluate the radioprotective effect of vitamin E and selenium separately and synergisticaly on human blood lymphocytes. Design : The study population consisted of 15 human volunteers will be that After taking the form of moral satisfaction from them , are divided into three groups. A group(each person 800mg Vitamin E before blood sampling) B group(each person 32mg Seenium before blood sampling) C group(each person 18 mg selenium and 400 mg vitamin E before blood sampling). They each receive the drug orally. Blood sampling done before and 1, 2 and 3 hours after receive the drug orally. After that, blood samples are irradiated with 2 Gy X-ray. Participants in the study were healthy and non-smokers with no specific disease. Finally chromosomal damage in human blood samples will be evaluated by micronuclei test.

General information

Acronym
no thing
IRCT registration information
IRCT registration number: **IRCT2015090123843N1**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2015-10-12, 1394/07/20

Registrant information
Name
Aram Rostami
Name of organization / entity
Iran university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2013-10-23, 1392/08/01
Expected recruitment end date
2014-05-22, 1393/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assesment of radioprotector effect of Selenium and Vitamin E synergically againt 6Mv X-ray in human blood lymphocyte by micronucli assay.

Public title
The effect of vitamin E and selenium to reduce the harmful effects of radiation
Purpose
Prevention
Inclusion/Exclusion criteria
People should be healthy and whitout any disease-specific and non-smokers
Age
From **22 years** old to **30 years** old
Gender
Male

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Chief of Assistance of Tehran University of Medical Sciences, 6 Floor, Central Building of Tehran University of Medical Sciences, Keshavarz Avenue,
City
Tehran
Postal code

Approval date
2014-02-14, 1392/11/25
Ethics committee reference number
24359

Health conditions studied

1

Description of health condition studied
Factors influencing health status and contact with health services
ICD-10 code
Z00
ICD-10 code description
General examination and investigation of persons without complaint and reported diagnosis

Primary outcomes

1

Description
Reduce Chromosomal Damage in Human's Volunteer Blood Lymphocytes
Timepoint
1 , 2 and 3 Hour after sampling
Method of measurement
Micronucli Assesment

Secondary outcomes

empty

Intervention groups

1

Description
Group A: each person will receive 800mg Vitamin E before blood sampling
Category
Treatment - Other

2

Description
Group B: Participants will receive 32mg Selenium before blood sampling
Category
Treatment - Drugs

3

Description
Group C: Participants will receive 18 mg selenium and 400 mg vitamin E before blood sampling
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiation Biology and Radiology Group of Tehran University of Medical Sciences
Full name of responsible person
Aram Rostami
Street address
Paramedicl Faculty of Tehran University of Medical Sciences, NO 4, Fardanesh Alley, 16 Azar Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Assistance of Tehran University of Medical Sciences
Full name of responsible person
Chief of Assistance

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Chief of Assistance of Tehran University of Medical Sciences, 6 Floor, Central Building of Tehran University of Medical Sciences, Keshavarz Avenue,
City
Tehran

Grant name
پایان نامه های کارشناسی ارشد

Grant code / Reference number
24359

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

Title of funding source
Research Assistance of Tehran University of Medical Sciences

Proportion provided by this source
100

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

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Position
Msc

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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