

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of vitamin E and C with placebo on level of double-stranded DNA breaks lymphocytes of in patients underwent CT scan with iodine contrast media: a clinical trial

Protocol summary

Summary

The aim of this study is the reduction of DNA Double Strand Break (DSB) in patients undergoing CT scan with Iodine Contrast Medium. This study is going to be run Randomized, double-label, and single-center, placebo-controlled. Thereafter, 60 patients that refer for abdomen/ pelvis CT scan to the Kashan's Shahid Beheshti Hospital will be chosen. The patients will be categorized into three groups including control, Vitamin C and Vitamin E groups using stratified block randomization method, based on the inclusion and exclusion criteria. After signing the written consent, patients in intervention groups receive the vitamin one hour before CT scan test. The blood sample is taken instantly after the CT scan from every individual patient. After separation and staining of the Lymphocytes, the number of breaks are counted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091029720N2**

Registration date: **2016-10-22, 1395/08/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-22, 1395/08/01

Registrant information

Name

Seyed Masoud Jafarpour

Name of organization / entity

Kashan University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5553 0353

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences.

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vitamin E and C with placebo on level of double-stranded DNA breaks lymphocytes of in patients underwent CT scan with iodine contrast media: a clinical trial

Public title

The effect of vitamin E and C on reducing CT scan damages.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: referring patients to the Radiology section of Kashan's Shahid Beheshti Hospital for abdomen/pelvis CT scan with Iodine Contrast Medium; Age Range of 18-65 years old. Exclusion criteria: patients under radiotherapy, chemotherapy or nuclear medicine

history during the last six months; diagnostic exposure three days before the test; suffering from leukemia of lymphoma; younger than 18 years or older than 65 years.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Patients are randomized into three groups through stratified block randomization.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

Qutbe ravandi Blvd,Kashan.

City

Kashan

Postal code**Approval date**

2016-02-20, 1394/12/01

Ethics committee reference number

IR.KAUMS.REC.1394.139

Health conditions studied**1****Description of health condition studied**

patients undergoing CTscan

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

DNA double strand breaks

Timepoint

Before and immediately after CTscan

Method of measurement

fluorescence microscope and count number of foci/cell

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Ascorbic Acid, 500 mg vitamin C, 1 hour before CT scan, single dose, Osvahpharma co.

Category

Treatment - Drugs

2**Description**

control group: Placebo, Starch, 1 hour before CT scan, single dose.

Category

Placebo

3**Description**

Intervention group 2: Alpha-Tocopherol, 400 IU vitamin E, 1 hour before CT scan, single dose, Zahravi laboratory

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan Shahid Beheshti Medical Center

Full name of responsible person

Dr Hamid Reza Talari

Street address

Qutbe ravandi Blvd,Kashan.

City

Kashan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Kashan University of

Medical Sciences

Full name of responsible person

Dr Gholamali Hamidi

Street address

Qutbe ravandi Blvd, Kashan.

City

Kashan

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 Kashan 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

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Mehran Mohseni

Position

PhD in medical physics

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