Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effect of vitamin C on apoptosis compared to control group on apoptosis in peripheral blood lymphocytes in patients treated with ablation in cardiac electrophysiology studies

Protocol summary

Summary

The aim of this study is to evaluate the radioprotective effect of vitamin C on apoptosis in peripheral blood lymphocytes of patients undergoing ablation in cardiac electrophysiology studies. This is a single blind study. For this reason, analyzer of information is unaware about the subject. Blocks of permutation (three blocks) used for the randomization. Inclusion criteria: Non-smoking; Lack of infectious disease; Do not use of antibiotics; Unexposed to ionizing radiation, 24 hours prior to sampling Exclusion criteria: Use of multivitamins; Use of alcohol; Acute or chronic disease A total number of 30 male and female patients aged 20 to 60 years will be selected in the same condition. Patients will be randomly divided into three groups. The first group of patients without vitamin C administration, in the second group, 3 hours before the test, 2 grams of vitamin c orally administered to patients as a tablet and the third group 3 hours before the test, one gram of vitamin c orally administered to patients as a tablet. Before intervention and after intervention within 24 hours after the test, 3 cc blood samples taken from the patients. Lymphocyte apoptosis will be evaluated by flow cytometry method. The ELISA method will be used to evaluate Bax and Bcl-2 proteins level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072529068N1**
Registration date: **2016-09-19, 1395/06/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-19, 1395/06/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitamin C on apoptosis compared to control group on apoptosis in peripheral blood lymphocytes in patients treated with ablation in cardiac electrophysiology studies

Public title

The effect of vitamin C on lymphocyte apoptosis induced by radiation

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Non-smoking; Lack of infectious disease; Do not use of antibiotics; Unexposed to ionizing radiation, 24 hours prior to sampling Exclusion criteria: Use of multivitamins; Use of alcohol; Acute or chronic disease
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Shiraz University of Medical Sciences
Street address
Central Building of Shiraz University of Medical Sciences
City
Shiraz
Postal code
Approval date
2016-06-26, 1395/04/06
Ethics committee reference number
IR.SUMS.REC.1395.44

Health conditions studied

1

Description of health condition studied
Patients treated with ablation in cardiac electrophysiology studies
ICD-10 code
IX
ICD-10 code description
Atrial fibrillation and flutter, Paroxysmal tachycardia

Primary outcomes

1

Description
apoptosis
Timepoint
Before the intervention and after intervention within 24 hours after the test
Method of measurement
Counting the number of apoptotic peripheral blood lymphocytes by flow cytometry

Secondary outcomes

1

Description
Bax protein
Timepoint
Before intervention and after intervention within 24 hours after the test
Method of measurement
Counting the number of Bax protein by ELISA method

2

Description
Bcl-2 protein
Timepoint
Before intervention and after intervention within 24 hours after the test
Method of measurement
Counting the number of Bcl-2 protein by ELISA method

Intervention groups

1

Description
Vitamin C (ascorbic acid), 1 gram oral tablet, only once in 3 hours prior to the test
Category
Prevention

2

Description
Vitamin C (ascorbic acid), 2 gram oral tablet, only once in 3 hours prior to the test
Category
Prevention

3

Description
The control group without action
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital of Shahid Faghihi

Full name of responsible person
Vahid Jorat (Cardiologist and associate professor)

Street address
Shahid Faghihi Hospital Angiography, Zand Street, Shiraz

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person
Seyed Basir Hashemi

Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz

City
Shiraz

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, Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
GholamHasan Hadadi

Position
Medical Physics PhD, Director of the Department of Radiology

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