

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effects of Vitamin E on cisplatin-induced nephrotoxicity in cancer patients treated with cisplatin-based chemotherapy

Protocol summary

Summary

Objective: Evaluation the effect of Vitamin E in prevention of Cisplatin-induced Nephrotoxicity. Design: Randomized, double-blind, placebo controlled clinical trial. Setting: Patients with cancer who were treated with cisplatin based chemotherapy regimen at Seyed-Al-Shohada Hospital affiliated to Isfahan University of Medical Sciences. Major Inclusion and Exclusion criteria: Patients aging ≥ 18 years and having glomerular filtration rate (GFR) > 80 ml/min will be enrolled in the study. Patients with comorbidity that affected renal function (such as diabetes mellitus, hypertension, and past history of renal dysfunction), previous chemotherapy, and treatment with other supplementation will be excluded. Intervention: Eligible patients will be randomized to drug and placebo groups. Patients in drug group will be received Vitamin E, 400Iu daily for 21 days starting before cisplatin treatment for 4 cycles. Main outcome measures: Changes in serum creatinine and the GFR compared with baseline value in each cycle after cisplatin treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701011497N5**
Registration date: **2017-01-15, 1395/10/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-15, 1395/10/26

Registrant information

Name

Sarah Mousavi

Name of organization / entity

Clinical Pharmacy Department, Pharmacy Faculty,
Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2567

Email address

smousavi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of Vitamin E on cisplatin-induced nephrotoxicity in cancer patients treated with cisplatin-based chemotherapy

Public title

Evaluation the effect of Vitamin E in prevention of cisplatin renal injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were age ≥ 18 years old and having glomerular filtration rate (GFR) > 80 ml/min. Exclusion

criteria were comorbidity that affected renal function (such as diabetes mellitus, hypertension, and past history of renal dysfunction); previous chemotherapy and treatment with other supplementation.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran, 81746 73461

City

Isfahan

Postal code

81746 73461

Approval date

2014-12-20, 1393/09/29

Ethics committee reference number

3514/9/D

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description

Changes in serum creatinine and the glomerular filtration rate

Timepoint

From cycle 1 to 4

Method of measurement

laboratory

Secondary outcomes

1

Description

changes in neutrophil gelatinase-associated lipocalin (NGAL) levels

Timepoint

From cycle 1 to 4

Method of measurement

Elisa kit

Intervention groups

1

Description

Patients in drug group will be received Vitamin E (Zahravi Pharmaceutical company, Tabriz, Iran), 400Iu daily for 21 days starting before cisplatin treatment for 4 cycles

Category

Treatment - Drugs

2

Description

Patients in control group will be received placebo of Vitamin E (Zahravi Pharmaceutical company, Tabriz, Iran), 400Iu daily for 21 days starting before cisplatin treatment for 4 cycles

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed-Al-Shohada Hospital

Full name of responsible person

Sarah Mousavi

Street address

Hezar Jerib avenue, Isfahan University of Medical Sciences, Seyed-Al-Shohada Hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Nematbakhsh

Street address

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Grant name

1333/9/12/پ

Grant code / Reference number

393870

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan 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**

Isfahan University of Medical Science

Full name of responsible person

Dr Sarah Mousavi

Position

PhD

Other areas of specialty/work**Street address**

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 3792 7072

Fax**Email**

s.mousavi@pharm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr Sarah Mousavi

Position

PhD

Other areas of specialty/work**Street address**

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 3792 7072

Fax**Email**

s.mousavi@pharm.mui.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr Sarah Mousavi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

73461-81746

Phone

+98 31 3792 7072

Fax**Email**

s.mousavi@pharm.mui.ac.ir

Web page address

mui.ac.ir

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