

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study the effect of vitamin E on cisplatin induced nephrotoxicity

Protocol summary

Study aim

Providing an appropriate treatment to reduce complications caused by cisplatin

Design

Clinical trial with control group, community based and pragmatic, with parallel groups, not blinded and randomization carried out by using table of numbers, consist of 30 patients in Phase 3 clinical trial

Settings and conduct

The study is conducted in the hematology department of the Sheikh Hospital and it has not been blinded

Participants/Inclusion and exclusion criteria

Patient satisfaction; Prescribing cisplatin for the patient; The absence of kidney disease and any renal failure;

Intervention groups

Intervention group: 15 patients with testicular tumors or head and neck tumors during the course of using cisplatin and 2 days after that they receive vitamin E at a dose of 400 units per day. Control group: 15 patients with testicular tumors or head and neck tumors who do not take vitamin E supplements during the use of cisplatin.

Main outcome variables

Urinary KIM-1 levels in urine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111024007892N8**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **retrospective**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1606 1227

Email address

azarfara@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of vitamin E on cisplatin induced nephrotoxicity

Public title

Study the effect of vitamin E on renal complications induced by cisplatin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Prescribing cisplatin for the patient Patient satisfaction

Exclusion criteria:

Age

From **6 months** old to **18 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description
Blinding is not done.

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Taheri Ave, Tohid Square, Dr. Sheikh Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

1358- 91735

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.MUMS.fm..REC.1395.652

Health conditions studied

1

Description of health condition studied

Testicular tumor

ICD-10 code

D40.7

ICD-10 code description

Other male genital organs

2

Description of health condition studied

Head and Neck tumor

ICD-10 code

C49.0

ICD-10 code description

Malignant neoplasm of connective and soft tissue of head, face and neck

Primary outcomes

1

Description

Urinalysis of KIM-1(Kidney Injuri Molecule)

Timepoint

At the beginning of the study and 2 days after the end of vitamin E consumption period

Method of measurement

KIM-1 (Kidney Injuri Molecule) kit of urine sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be given an E Vigel capsule (Dana Pharmacy) at a dose of 400 units daily for up to two days after completion of cisplatin treatment.

Category

Treatment - Other

2

Description

Control group: Patients in the control group not given any substance.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dr.Sheikh Hospital

Full name of responsible person

Anoosh Azarfar

Street address

Taheri Ave, Tohid Square, Dr. Sheikh Hospital

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Email

azarfara@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

دکتر محسن تفقدي

Street address

Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street

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Mashhad

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Razavi Khorasan

Postal code

91778-99191

Phone

+98 51 3841 1538

Email

ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

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

Iman jafarzadeh fadaki

Position

Medical physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Anoosh Azarfar

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Full name of responsible person

Anoosh Azarfar

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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