

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A double blind clinical trial for study of preventive effect of selenium in cisplatin induced nephrotoxicity

Protocol summary

Summary

Cisplatin is one of the most useful cytotoxic drugs in the treatment of cancers but its clinical use is associated with nephrotoxicity. In the present study, we investigated the preventive effect of selenium in cisplatin induced nephrotoxicity. Eighty patients who were candidates to receive cisplatin for chemotherapy, randomly divided into two groups. The first group received selenium 400 microgram 24 hours before cisplatin infusion. The second group received placebo with the same mode. Serum Creatinine was measured before and the 5th day of cisplatin infusion. Acute renal failure was the main outcome of our study defined as an increase in serum Creatinine more than 0.5 mg/dl. After data collection we compared the incidence of acute renal failure in these two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901213678N1**

Registration date: **2010-02-20, 1388/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

Name

Abazar Parsi

Name of organization / entity

Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1374 3013

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dr_abazar_parsi@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Ahvaz Jundishapur university of medical sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blind clinical trial for study of preventive effect of selenium in cisplatin induced nephrotoxicity

Public title

Study of preventive effect of selenium in cisplatin induced nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who were referred to Shafa hospital for chemotherapy with Cisplatin 1388-1389
Exclusion criteria: 1) serum Creatinine more than 1.5mg/dl in man and more than 1.4mg/dl in woman 2) Use of other nephrotoxic drug such as NSAID, ACEI, Aminoglycoside at 2 weeks later 3) Sepsis 4) Pancytopenia 5) Patient who refused Selenium

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**

Target sample size: 80

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 Ahvaz Jundishapur university of medical sciences

Street address

Ahvaz Jundishapur university of medical sciences

City

Ahvaz

Postal code**Approval date**

2010-03-06, 1388/12/15

Ethics committee reference number

/8/20//5039

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

Acute renal failure due to Cisplatin

ICD-10 code

N14

ICD-10 code description

Drug- and heavy-metal-induced tubulo-interstitial and tubular conditions

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

Serum creatinine changes

Timepoint

Before and the 5th day after cisplatin infusion

Method of measurement

Enzyme assay

Secondary outcomes

empty

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

Use of placebo in control group at first day of admission

Category

Placebo

2**Description**

Use of selenium (400 microgram) at the first day of admission

Category

Prevention

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

Shafa hospital

Full name of responsible person**Street address****City**

Ahvaz

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

Research deputy of Ahvaz Jundishapur university of medical sciences

Full name of responsible person

Dr Ali Ghorbani

Street address

Intenal medicine ward, Golestan hospital

City

Ahvaz

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

Yes

Title of funding source

Research deputy of Ahvaz Jundishapur 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

Ahvaz jundishapur university of medical sciences

Full name of responsible person

Dr Abazar Parsi

Position

Internal medicine resident

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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