

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Normobaric hyperoxia preconditioning ameliorates cisplatin nephrotoxicity: a pilot prospective case-control study

#### Protocol summary

##### Summary

**Aims:** The aim of the present study was to examine whether preconditioning with normobaric hyperoxia would prevent cisplatin-induced nephrotoxicity in patients with solid tumor. **Methods:** Twenty-one adult patients with solid tumor treated with cisplatin were entered in this pilot and prospective study between Feb 2009 and Nov 2009. **Inclusion criteria:** the patients who treated with cisplatin due to cancer. **Exclusion criteria:** The patients who had chronic obstructive lung disease, pneumothorax, upper respiratory infection, fever, viral infection, history of seizure, pregnancy, optic nerve inflammation, history of ear surgery and history of heavy cigarette smoking were excluded from this study. Ten patients were exposed to pure oxygen via non-rebreathing reservoir mask which increased the provided oxygen rate to 60% oxygen for 2 hours at 48, 24 and 6 hours before intravenous administration of cisplatin. Venous blood samples were obtained from all patients for serum urea and creatinine (Cr) measurements as primary outcome on day 1 before and days 2 and 5 days after cisplatin exposures. The renal function was also measured with the glomerular filtration rate (GFR) estimated by the Cockcroft-Gault equation [ $GFR = (140 - \text{age}) \times (\text{Wt in kg}) \times (0.85 \text{ if female}) / (72 \times \text{Cr})$ ]. Docetaxel (trade name Taxotere) was given 75 mg/m<sup>2</sup> intravenous on day 1; consequently cisplatin was administered 50 mg/m<sup>2</sup> at the second day and 2-3 L of normal saline was infused on the day of cisplatin administration. All patients received 5-FU 350 mg/m<sup>2</sup> for five days after injection of cisplatin.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102065775N1**

Registration date: **2011-04-10, 1390/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-10, 1390/01/21

##### Registrant information

###### Name

behzad Einollahi

###### Name of organization / entity

Baqiyatallah

###### Country

Iran (Islamic Republic of)

###### Phone

+98 88037667

###### Email address

einollahi@ijnu.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Baqiyatallah University of Medical Sciences

##### Expected recruitment start date

2009-02-01, 1387/11/13

##### Expected recruitment end date

2009-11-01, 1388/08/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Normobaric hyperoxia preconditioning ameliorates cisplatin nephrotoxicity: a pilot prospective case-control study

##### Public title

Normobaric hyperoxia preconditioning ameliorates cisplatin nephrotoxicity: a pilot prospective case-control study

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: the patients who treated with cisplatin due to cancer Exclusion criteria: The patients who had chronic obstructive lung disease, pneumothorax, upper respiratory infection, fever, viral infection, history of seizure, optic nerve inflammation, history of ear surgery and history of heavy cigarette smoking were excluded from this study. None of female patients was pregnant.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 21

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Ethics committee of Baqiyatallah University

##### Street address

Baqiyatallah Hospital

##### City

Tehran

##### Postal code

#### Approval date

2008-06-02, 1387/03/13

#### Ethics committee reference number

13873/29---340/22/س

## Health conditions studied

### 1

#### Description of health condition studied

Acute renal failure

#### ICD-10 code

N17

## ICD-10 code description

Acute renal failure

## Primary outcomes

### 1

#### Description

Serum Creatinine

#### Timepoint

0, 6,24,48

#### Method of measurement

Serum creatinine measurement previous day and 6, 24, 48 hours after Hyperoxia preconditioning

## Secondary outcomes

### 1

#### Description

eGFR decrementation

#### Timepoint

-1, 0, 2, 5 days after treatment

#### Method of measurement

plasma creatinine for GFR estimation in all patients in-1, 0, 2 and 5 days after cisplatin exposures.

## Intervention groups

### 1

#### Description

pure oxygen 60% via non-rebreathing reservoir mask for 2 hours at 48, 24 and 6 hours before intravenous administration of cisplatin.

#### Category

Prevention

### 2

#### Description

Docetaxel (trade name Taxotere) was given 75 mg/m<sup>2</sup> intravenous on day 1

#### Category

Prevention

### 3

#### Description

2-3 Liter of normal saline intravenous on the day of cisplatin administration during 4-6 hours

#### Category

Prevention

### 4

#### Description

cisplatin 50 mg/m<sup>2</sup> at the second day intravenous

#### Category

Treatment - Drugs

## 5

### Description

5-FU 350 mg/m<sup>2</sup> intravenous for five days after injection of cisplatin.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nephrology and Urology Research Center,  
Baqiyatallah University of Medical Sciences

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Nephrology and Urology Research Center,  
Baqiyatallah University of Medical Sciences

##### Full name of responsible person

Behzad Einollahi

##### Street address

Ground Floor of Baqiyatallah Hospital, Baqiyatallah  
Medical University, Mollasdra Ave., Vanak Squ.,  
Tehran, Iran; Nephrology and Urology Research  
Center, Baqiyatallah University of Medical Sciences

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Nephrology and Urology Research Center, Baqiyatallah  
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

Nephrology and Urology Research Center,  
Baqiyatallah University of Medical Sciences

##### Full name of responsible person

Behzad Einollahi

##### Position

Professor of Nephrology

##### Other areas of specialty/work

##### Street address

Nephrology and Urology Research Center,  
Baqiyatallah University of Medical Sciences

##### City

Tehran

##### Postal code

##### Phone

+98 21 8126 2073

##### Fax

##### Email

einollahi@ijnu.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Nephrology and Urology Research Center,  
Baqiyatallah University of Medical Sciences

##### Full name of responsible person

Behzad Einollahi

##### Position

Professor of Nephrology

##### Other areas of specialty/work

##### Street address

Nephrology and Urology Research Center,  
Baqiyatallah University of Medical Sciences

##### City

Tehran

##### Postal code

##### Phone

+98 21 8126 2073

##### Fax

##### Email

einollahi@ijnu.ir

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

##### Full name of responsible person

Behzad Einollahi

##### Position

##### Other areas of specialty/work

##### Street address

##### City

##### Postal code

##### Phone

##### Fax

##### Email

##### Web page address

## **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*