

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/m² intravenous on day 1; consequently cisplatin was administered 50 mg/m² 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/m² 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/m² 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/m² at the second day intravenous

Category

Treatment - Drugs

5

Description

5-FU 350 mg/m² 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

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Person responsible for updating data

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Full name of responsible person

Behzad Einollahi

Position

Other areas of specialty/work

Street address

City

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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