

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of protective effects of silymarin on cisplatin induced nephrotoxicity in patients with upper gastrointestinal adenocarcinoma

#### Protocol summary

##### Summary

Cisplatin is a potent chemotherapeutic agent that has been widely used to treat many solid tumours. acute renal failure, despite conservative fluid and electrolyte management, frequently reported adverse event and limiting cisplatin use. Silymarin, a flavonolignan complex isolated from *Silybum marianum*, has a strong antioxidant, hepatoprotective, anticancer and in animal model nephroprotective properties. Neutrophil gelatinase-associated lipocalin (NGAL) protein is a promising biomarker to detect acute kidney injury due to cisplatin. The aim of present study, a randomized double-blind placebo- controlled clinical trial, to investigate the therapeutic effect of silymarin on cisplatin induced nephrotoxicity and its impact on chemotherapy. fifty-eight patients with diagnosed upper gastrointestinal tract carcinomas randomized to silymarin (520mg) or placebo plus chemotherapy (cisplatin 50-60 mg/m<sup>2</sup>, 5-FU 750 mg/m<sup>2</sup>, docetaxel 60-80 mg/m<sup>2</sup> every 21 days) for 63 days after inclusion. serum creatinine, BUN and electrolyte, NGAL, VEGF, caspase activity assessed at the beginning during and the end of the trial.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207013043N6**  
Registration date: **2012-09-09, 1391/06/19**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-09-09, 1391/06/19

##### Registrant information

**Name**

Simin Dashti-Khavidaki

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

dashtis@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Science

##### Expected recruitment start date

2012-08-01, 1391/05/11

##### Expected recruitment end date

2014-08-01, 1393/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of protective effects of silymarin on cisplatin induced nephrotoxicity in patients with upper gastrointestinal adenocarcinoma

##### Public title

silymarin and cisplatin induced nephrotoxicity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria (age > 18 years; diagnosed and measurable upper gastrointestinal adenocarcinoma; no swallow problem; would like to participate in the study; GFR > 45 ml/min/1.73 m<sup>2</sup>) Exclusion criteria (end stage renal disease, requiring dialysis, post transplantation; receiving contrast media during last 72 hours; chronic

use of corticosteroids; chronic use of ACEI; untreated hypo-and hyperthyroidism; ejection fraction<60%; active urinary tract infection; iver disease (5fold increase of liver enzyme in asymptomatic or 3 fold increase in syptomatic; ; use of other nephrotoxic agents such as aminoglycoside, amphotricin; karnofsky performance status <70)

#### Age

From **18 years** old to **139 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **58**

#### 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

tehran university of medical science

###### Street address

16 azar Avn. tehran university of medical science

###### City

tehran

###### Postal code

o21

##### Approval date

2010-09-23, 1389/07/01

##### Ethics committee reference number

91-03-33-18878

### Health conditions studied

#### 1

##### Description of health condition studied

oesophagus cancer

##### ICD-10 code

C15

##### ICD-10 code description

Malignant neoplasm of oesophagus

#### 2

##### Description of health condition studied

Stomach Cancer

##### ICD-10 code

C16

##### ICD-10 code description

Malignant neoplasm of stomach

### Primary outcomes

#### 1

##### Description

urine neutrophil gelatinase-associated lipocalin (NGAL)

##### Timepoint

before chemotherapy and at 6,24 hours after first and third cycle of chemotherapy, day 21 before second cycle

##### Method of measurement

ELISA kit

#### 2

##### Description

serum concentration of VEGF and tissue activity of caspase 3

##### Timepoint

after recruitment and the end of study after three chemotherapy cycle

##### Method of measurement

ELISA kit

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

silymarin 420 mg daily in three divided doses for 65 days along with standard chemotherapy [cisplatin 50-60mg/m2 +5-FU 750 mg/m2 +docetaxel 60-80 mg/m2 control]

##### Category

Treatment - Drugs

#### 2

##### Description

placebo 420 mg daily in three divided doses for 65 days as control along with chemotherapy same as intervention

##### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

Name of recruitment center

cancer institute, imam khomeini hospital  
**Full name of responsible person**  
Dr. sanambar sadighi  
**Street address**  
cancer institute imam khomeini hospital  
**City**  
tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
tehran university of medical science,  
**Full name of responsible person**  
Dr.sanambar sadighi, Dr.simin dashti  
**Street address**  
cancer institute of tehran, Urology and Nephrology  
Research Center  
**City**  
tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
tehran university of medical science,  
**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

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
dep.clinical pharmacy, tehran university of medical science  
**Full name of responsible person**  
Dr. simin dashti-khavidaki

**Position**  
clinical pharmacist  
**Other areas of specialty/work**  
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dep.clinical pharmacy, tehran university of medical science  
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+98 21 6695 4709  
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dashtis@tums.ac.i  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
tums  
**Full name of responsible person**  
foroud shahbazi  
**Position**  
resident  
**Other areas of specialty/work**  
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16 azar Avn. tums  
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00  
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foroud08@gmail.com  
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## 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*