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 manegement, 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 it's impact on chemotherapy. fifty-eight patients with diagnosed upper gasterointestinal tract carcinomal randomized to silymarin (520mg) or placebo plus chemotherapy (cisplatin 50-60 mg/m2, 5-FU750 mg/m2, docetaxel 60-80 mg/m2 every 21 days) for 63 day after inclusion. serum creatinin, 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 measurale upper gasterointestinal adenocarcinoma; no swallow problem; would like to participate in the study; GFR>45ml/min/1.73m2) 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

Street address

dep.clinical pharmacy, tehran university of medical science

City

tehran

Postal code

Phone

+98 21 6695 4709

Fax

Email

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

Street address

16 azar Avn. tums

City

tehran

Postal code

Phone

00

Fax

Email

foroud08@gmail.com

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