Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

investigating the effect of atorvastatin on the cisplatin induced nephrotoxicity in patients with solid tumors

Protocol summary

Study aim

1)Determination of mean serum creatinine levels, potassium, magnesuim ،BUN and Glomerular filteration rate in patients receiving Cisplatin and patients receiving Cisplatin plus atorvastatin and comparison of both groups

Design

randomized clinical trial, with parallel groups, triple blinded, phase 3, using block randomization

Settings and conduct

setting: Oncology department at Amir Hospital of Shiraz University of Medical Sciences Triple blind including patients, care providers and data analyser

Participants/Inclusion and exclusion criteria

Inclusion criteria: New cases of patients with solid tumors under Cisplatin therapy, minimum age of 18و glomerular filtration rate (GFR) > 60 ml/min, serum creatinine less than 1.5 mg/dl and both sexes will be included in the study. Exclusion criteria: Patients who used cisplatin less than 50mg/m2 or divided dose of cisplatin in several days will be excluded in this study. Also patients with a past history of Cisplatin therapy, chronic kidney disease, NSAIDS usage or using any nephrotoxic drugs

Intervention groups

In both groups patients receive 12.5-25 gr manitol in addition to antiemetic medication before receiving cisplatin. Cisplatin infuse in 500 cc chloride serum (N/S) in 1-2 hrs then after finishing infusion of cisplatin the patient hydrate with 500 cc N/S. In second group who receive atorvastatin 40 mg,1 hour before cisplatin administration then continue atorvastatin daily till 7 days after starting cisplatin. patients in first group will recieve placebo like this shedule

Main outcome variables

measuring serum creatinine, BUN, Mg and K at days 1, 8, 21

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140605017982N2**
Registration date: **2020-06-05, 1399/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-05, 1399/03/16**
Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name
Nasrin Namdari
Name of organization / entity
Shiraz University Of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 71 1647 4301
Email address
namdari_n@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
investigating the effect of atorvastatin on the cisplatin induced nephrotoxicity in patients with solid tumors

Public title
investigating the effect of atorvastatin on the cisplatin induced nephrotoxicity

Purpose
Screening

Inclusion/Exclusion criteria

Inclusion criteria:
New cases of patients with solid tumors under Cisplatin therapy, minimum age of 18 glomerular filtration rate(GFR) > 60 ml/min serum creatinine less than 1.5 mg/dl

Exclusion criteria:
Patients who used cisplatin less than 50mg/m2 or divided dose of cisplatin in several days patients with a past history of Cisplatin therapy, chronic kidney disease, NSAIDS usage or using any nephrotoxic drugs will not participate in this study patients with a history of NSAIDS usage or using any nephrotoxic drugs will not participate in this study patients with a historyof chronic kidney disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **3**
blood(clot) sample for BUN, cr, K, Mg on days 1, 8 and 21

Randomization (investigator's opinion)
Randomized

Randomization description
randomization will done by blocked randomization method.random blocks of 4 subjects were used. a computer random number generator will generate the sequence of blocks(spss version24, chicago,us). randomization will done by a resident and only he will aware of patients group

Blinding (investigator's opinion)
Triple blinded

Blinding description
we prepared the main drug (atorvastatin) and placebo in 2 different colour of boxes. The patient , care provider and data analyser were blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University Of Medical Science

Street address
Bone Marrow Transplant Ward, Namazee Hospital, Namazee Square, Shiraz

City
Shiraz

Province
Fars

Postal code
7186766781

Approval date
2019-01-14, 1397/10/24

Ethics committee reference number
IR.SUMS.MED.REC.1398.024

Health conditions studied

1

Description of health condition studied
Cisplatin nephrotoxicity

ICD-10 code
N17.9

ICD-10 code description
Acute kidney failure, unspecified

Primary outcomes

1

Description
percentage of people with renal failure

Timepoint
measurement of blood Urea nitrogen, creatinine, potassium, magnesium before intervention and 8 and 21 days after intervention

Method of measurement
measurement of blood Urea nitrogen, creatinine, potassium, magnesium

Secondary outcomes

empty

Intervention groups

1

Description
Atorvastatin(sobhan) 40 mg,1 hour before cisplatin administration then continue atorvastatin daily till 7 days

after starting cisplatin.

Category

Treatment - Drugs

2

Description

Control group: placebo starts 1 hour before starting cisplatin, continue daily for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Oncology Hospital

Full name of responsible person

Nasrin Namdari

Street address

Amir Oncology Hospital, Farhang shahr Street, Shiraz,

City

Shiraz

Province

Fars

Postal code

7186766781

Phone

+98 71 3647 4301

Email

namdari_n@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Research and Technology Assistance

Street address

Reasearch and technology assistance, Shiraz university Of medical Science, Namazee Square<, shiraz

City

Shiraz

Province

Fars

Postal code

7186766781

Phone

+98 71 3230 5410

Email

namdrai_n@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Namdari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Oncology

Street address

Bone Marrow Transplant, Namazee Hospital, Namazee Square, Shiraz

City

Shiraz

Province

Fars

Postal code

7186766781

Phone

+98 71 3647 4301

Email

namdari_n@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Namdari

Position

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City

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Province

Fars

Postal code
7186766781
Phone
+98 71 3647 4301
Email
namdari_n@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Namdari Nasrin
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Oncology
Street address
Bone Marrow Transplant Ward, Namazee Hospital, namazee square, Shiraz
City
Shiraz
Province
Fars
Postal code
7186766781
Phone
+98 71 3647 4301
Email
namdari_n@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available