

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of acute hematologic and renal toxicities in two chemotherapy schedules of cisplatin for epithelial cell carcinoma of head and neck

#### Protocol summary

##### Study aim

comparison of acute hematologic and renal toxicities in two schedules of weekly and three weekly cisplatin in chemoradiation of epithelial carcinoma of head and neck

##### Design

This is a Phase 2 clinical trial. The sample size was calculated based on the difference in leukopenia between the two groups. According to previous studies, 50 subjects in each group were calculated. Patients are stratified based on age, primary location of the disease, intent of treatment (adjuvant or definitive) and prior induction chemotherapy, and then using permuted block random method technique, they were randomized in two weekly 40mg/m<sup>2</sup> and three weekly 100mg/m<sup>2</sup> cisplatin arms.

##### Settings and conduct

The study was conducted among head and neck patients referred to the oncology department of Imam Hossein Hospital.

##### Participants/Inclusion and exclusion criteria

epithelial carcinoma of head and neck that are candidate for concurrent chemoradiation stage 3,4 of the disease aged 20-75 years old ECOG performance status 0-2 no prior radiation therapy and chemotherapy normal organs function no active multiple primary cancers no uncontrolled comorbidities

##### Intervention groups

The control group consisted of patients treated with a regimen of cisplatin 100mg / m<sup>2</sup> every three weeks. The intervention group included patients treated with 40 mg / m<sup>2</sup> of cisplatin weekly.

##### Main outcome variables

changes in leukocyte, neutrophil, lymphocyte, hemoglobin, platelet treatment compliance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180223038829N1**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **retrospective**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

##### Registration date

2018-03-12, 1396/12/21

##### Registrant information

##### Name

Shokoufe Norouzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8842 6899

##### Email address

shokoufe.norouzi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

2016-03-20, 1395/01/01

##### Actual recruitment end date

2017-11-22, 1396/09/01

##### Trial completion date

empty

## Scientific title

Comparison of acute hematologic and renal toxicities in two chemotherapy schedules of cisplatin for epithelial cell carcinoma of head and neck

## Public title

Comparison of two protocol chemotherapy for cisplatin

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

histologically proven malignancy in resected specimen all epithelial carcinoma of head and neck that needs concurrent chemoradiation stages 3,4 of the disease aged 20-75 years old ECOG Performance Status :0-2 no prior radiation therapy or chemotherapy adequate organ function written informed consent

### Exclusion criteria:

active multiple primary cancers; synchronous or metachronous within 5 years infection requiring systemic treatment women who are or may be pregnant psychosis or psychiatric symptoms/signs that judged to male participation in the study difficult uncontrolled diabetes mellitus uncontrolled hypertension

## Age

From **20 years** old to **75 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

Actual sample size reached: **77**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Stratified randomization

## 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 shahid Beheshti University of Medical Sciences

##### Street address

Next to Taleghani Hospital, Yemeni Ave, Shahid

Chamran Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1985717443

#### Approval date

2016-07-19, 1395/04/29

#### Ethics committee reference number

IR.SBMU.MSP.REC.1395.161

## Health conditions studied

### 1

#### Description of health condition studied

epithelial carcinoma of head and neck

#### ICD-10 code

C00-C14

#### ICD-10 code description

Malignant neoplasms of lip, oral cavity and pharynx

## Primary outcomes

### 1

#### Description

leukocyte

#### Timepoint

weekly

#### Method of measurement

blood serum level

### 2

#### Description

lymphocyte

#### Timepoint

weekly

#### Method of measurement

blood serum level

### 3

#### Description

neutrophil

#### Timepoint

weekly

#### Method of measurement

blood serum level

### 4

#### Description

hemoglobin

#### Timepoint

weekly

#### Method of measurement

blood serum level

## 5

### Description

platelet

### Timepoint

weekly

### Method of measurement

blood serum level

## 6

### Description

creatinin

### Timepoint

weekly

### Method of measurement

blood serum level

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: weekly schedules of cisplatin

#### Category

Treatment - Drugs

### 2

#### Description

Control group: three weekly schedule of cisplatin

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Hossein Hospital

##### Full name of responsible person

shokoufe Norouzi

##### Street address

No 10, Far Alley, Farhang Alley, Hamid Alley,  
Dr.Shariati Ave, Tehran Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1639643413

##### Phone

+98 21 8842 6899

##### Email

shokoufe.norouzi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Deputy of research and technology

##### Street address

Emam Hossein Hospital, Shahis Madani Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7343 2475

##### Email

shokoufe.norouzi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

shokoufe Norouzi

##### Position

Resident of radiation oncology

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Radiotherapy

##### Street address

No 10, Far Alley, Farhang Alley, Hamid Alley,  
Dr.Shariati Ave, Tehran Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1639643413

**Phone**

+98 21 8842 6899

**Email**

shokoufe.norouzi@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

shokoufe Norouzi

**Position**

Resident of radiation oncology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

No 10, Far Alley, Farhang Alley, Hamid Alley,  
Dr.Shariati Ave, Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1639643413

**Phone**

+98 21 8842 6899

**Email**

shokoufe.norouzi@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

shokoufe Norouzi

**Position**

Resident of radiation oncology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

No 10, Far Alley, Farhang Alley, Hamid Alley,  
Dr.Shariati Ave, Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1639643413

**Phone**

+98 21 8842 6899

**Email**

shokoufe.norouzi@yahoo.com

**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