Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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/m2 and three weekly 100mg/m2 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 / m2 every three weeks The intervention group included patients treated with 40 mg / m2 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 chemoraradiation 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
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1639643413
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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
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1617763141
Phone
+98 21 7343 2475
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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
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No 10, Far Alley, Farhang Alley, Hamid Alley, Dr.Shariati Ave, Tehran Town
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Resident of radiation oncology
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Person responsible for updating data

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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