Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The comparison of acute toxicities and loading dose of drug in weekly and three - weekly Cisplatin delivered concomitant with radiotherapy in Squamous cell carcinoma of head and neck.

Protocol summary

Summary

The goal of this trial is comparison between weekly and three - weekly Cisplatin delivered concomitant with radiotherapy.The Inclusion criteria is Pathologic report of Squamous.cell.carcinoma ; Age 18- 70 years ; ECOG performance status of 0-1; No distant metastasis; WBC equal to more than 4000; PLT equal to more than 100000; Hb equal to more than 10; Serum Cr less than 1.5 ; Serum aminotransferase less than twice of normal range and the Exclusion criteria is sever medical or psychiatric disorder; Patient who dose not have a good fallow up.All patients in this trial have a Squamous cell carcinoma of the head and neck.Sample size in weekly arm is 45 patients and in three- weekly arm is 45 patients too.In the first group Cisplatin dose is 40 mg/m2 once per week , and in second group 100mg/m2 every three weeks, is administered concomitant with radiotherapy.Hematologic, GI and Renal complications , Fever , Sensory neuropathy and Hypersensitivity reactions will be checked once per week in first arm and every three week in the second arm.Comparison of complications will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112225185N1**
Registration date: **2015-12-05, 1394/09/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-05, 1394/09/14

Registrant information

Name
Somaye Barihi
Name of organization / entity
Ahvaz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Ahvaz University Of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of acute toxicities and loading dose of drug in weekly and three - weekly Cisplatin delivered concomitant with radiotherapy in Squamous cell carcinoma of head and neck.

Public title

Complication assessment of chemotherapy with radiotherapy in head and neck tumors

Purpose

Treatment

Inclusion/Exclusion criteria

(Inclusion criteria: Pathologic report of

Squamous.cell.carcinoma ; Age 18- 70 years ; ECOG performance status of 0-1; No distant metastasis; WBC equal to more than 4000; PLT equal to more than 100000; Hb equal to more than 10; Serum Cr less than 1.5 ; Serum aminotransferase less than twice of normal range.) (Exclusion criteria: Sever medical or psychiatric disorder; Patient who dose not have a good fallow up.)

Age
From **75 years** old to **23 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Ahvaz University Of Medical Sciences

Street address
Golestan, Ahvaz, Khozestan

City
Ahvaz

Postal code

Approval date
2015-03-10, 1393/12/19

Ethics committee reference number
ajums.REC.1393.382

Health conditions studied

1

Description of health condition studied
Head and neck tumor

ICD-10 code
C00

ICD-10 code description
Malignant neoplasm of lip

2

Description of health condition studied
Head and neck tumor

ICD-10 code
C01

ICD-10 code description
Malignant neoplasm of base of tongue

3

Description of health condition studied
Head and neck tumor

ICD-10 code
C03

ICD-10 code description
Malignant neoplasm of gum

4

Description of health condition studied
Head and neck tumor

ICD-10 code
C02

ICD-10 code description
Malignant neoplasm of other and unspecified parts of tongue

5

Description of health condition studied
Head and neck tumor

ICD-10 code
C04

ICD-10 code description
Malignant neoplasm of floor of mouth

6

Description of health condition studied
Head and neck tumor

ICD-10 code
C05

ICD-10 code description
Malignant neoplasm of palate

7

Description of health condition studied
Head and neck tumor

ICD-10 code
C06

ICD-10 code description
Malignant neoplasm of other and unspecified parts of mouth

8

Description of health condition studied
Head and neck tumor

ICD-10 code
C10

ICD-10 code description
Malignant neoplasm of oropharynx

9

Description of health condition studied
Head and neck tumor
ICD-10 code
C11
ICD-10 code description
Malignant neoplasm of nasopharynx

10

Description of health condition studied
Head and neck tumor
ICD-10 code
C12
ICD-10 code description
Malignant neoplasm of piriform sinus

11

Description of health condition studied
Head and neck tumor
ICD-10 code
C13
ICD-10 code description
Malignant neoplasm of hypopharynx

12

Description of health condition studied
Head and neck tumor
ICD-10 code
C14
ICD-10 code description
Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx

Primary outcomes

1

Description
Hematologic disorders
Timepoint
Befor start of treatment then weekly in first group and three weekly in second group
Method of measurement
CBC markers

2

Description
Neutropenic fever
Timepoint
Befor start of treatment then weekly in first group and three weekly in second group
Method of measurement
CBC markers and oral temperature

3

Description
Renal disorders
Timepoint
Befor start of treatment then weekly in first group and three weekly in second group
Method of measurement
Serum Cr

4

Description
GI disorders
Timepoint
Befor start of treatment then weekly in first group and three weekly in second group
Method of measurement
Clinical presentation of acute and chronic nausea and vomiting /oral mucositis/more than twice of normal range of liver enzymes

5

Description
Stopping the treatment
Timepoint
During treatment time
Method of measurement
With each complications

6

Description
Hypersensitivity reaction
Timepoint
Befor start of treatment then weekly in first group and three weekly in second group
Method of measurement
Clinical presentation

7

Description
Sensory neuropathy
Timepoint
Befor start of treatment then weekly in first group and three weekly in second group
Method of measurement
Clinical presentation of paresthesia in hands and feet

8

Description
Accumulative dose
Timepoint
End of treatment
Method of measurement
Accumulation of all drug doses during treatment

Secondary outcomes

1

Description
Stage of disease
Timepoint

Start of treatment

Method of measurement

TNM system

Intervention groups

1

Description

In the first group IV Cisplatin will be administered with the dose of 40 mg/ m2 once weekly concurrently with radiotherapy

Category

Treatment - Drugs

2

Description

In the second group IV Cisplatin will be administered three- weekly with the dose of 100 mg/m2 concurrently with radiotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz, Golestan Hospital, Radiotherapy Ward

Full name of responsible person

Dr Somaye.Barihi Assistant Of Radiation Oncology

Street address

Radiotherapy Ward, Golestan Hospital, Ahvaz, Khozestan

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University Of Medical Sciences

Full name of responsible person

Dr Hojatoalah Shahbazian

Street address

University Of Medical Sciences, Ahvaz, Khozestan

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University Of Medical Sciences

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

Name of organization / entity

Ahvaz, Golestan Hospital,Radiotherapy Ward

Full name of responsible person

Dr Hojatolah Shahbazian

Position

Radiation Oncologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Hojaolah Shahbazian

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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