

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Radiologic response rate of chemoradiotherapy in inoperable head and neck squamous cell carcinoma; weekly versus triweekly cisplatin schedule

Protocol summary

Summary

The goal of this trial is to compare radiologic response rate between weekly and triweekly Cisplatin delivered concomitant with radiotherapy. The Inclusion criteria is histopathologically confirmed 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 follow up. No operation was done for patients before enrolling in the trial. Sample size in weekly arm in nasopharyngeal carcinoma is 7 patients and in nonnasopharyngeal is 24 patients. In triweekly arm in nasopharyngeal carcinoma, the sample size is 11 patients and in non-nasopharyngeal is 21 patients. In the first group Cisplatin dose is 40 mg/m² once per week , and in second group 100mg/m² every three weeks, which is administered concomitant with radiotherapy. The comparison between radiologic response rate in two groups will be done after 8-10 weeks of radiotherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041125211N1**

Registration date: **2016-04-11, 1395/01/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-11, 1395/01/23

Registrant information

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Name of organization / entity

Ahvaz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz University Of Medical Sciences

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiologic response rate of chemoradiotherapy in inoperable head and neck squamous cell carcinoma; weekly versus triweekly cisplatin schedule

Public title

Radiologic response rate of chemotherapy with radiotherapy in previously inoperable 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 **23 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **63**

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

Radiotherapy Ward, Golestan Hospital,

City

Ahvaz

Postal code

Approval date

2014-12-27, 1393/10/06

Ethics committee reference number

ajums.REC.1393.383

Health conditions studied

1

Description of health condition studied

Head and neck tumor

ICD-10 code

C10

ICD-10 code description

Malignant neoplasm of oropharynx

2

Description of health condition studied

Head and neck tumor

ICD-10 code

C05

ICD-10 code description

Malignant neoplasm of palate

3

Description of health condition studied

Head and neck tumor

ICD-10 code

C04

ICD-10 code description

Malignant neoplasm of floor of mouth

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

C06

ICD-10 code description

Malignant neoplasm of other and unspecified parts of mouth

6

Description of health condition studied

Head and neck tumor

ICD-10 code

C03

ICD-10 code description

Malignant neoplasm of gum

7

Description of health condition studied

Head and neck tumor

ICD-10 code

C00

ICD-10 code description

Malignant neoplasm of lip

8

Description of health condition studied

Head and neck tumor

ICD-10 code

C01

ICD-10 code description

Malignant neoplasm of base of tongue

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

Radiologic response rate

Timepoint

Before start of treatment and after 8-10 week of radiotherapy

Method of measurement

CTscan

Secondary outcomes

1

Description

Stage of disease

Timepoint

Start of treatment

Method of measurement

TNM system

2

Description

Tumor differentiation

Timepoint

Start of treatment

Method of measurement

Pathologic report

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 triweekly 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. maedeh Berahman Assistant Of Radiation Oncology

Street address

Radiotherapy Ward, Golestan Hospital, Ahvaz, Khozestan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University Of Medical Sciences

Full name of responsible person

Dr Hojatoolah Shahbazian

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Radiotherapy Ward, Golestan Hospital, 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

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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