

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Complication assessment of concurrent chemoradiotherapy with 100 mg/m2 continuous dose vs 100 mg/m2 divided into three consecutive days in patients with head and neck squamous cell carcinoma , A Randomized clinical trial

Protocol summary

Study aim

Complication assessment of concurrent chemoradiotherapy with 100 mg/m2 continuous dose vs 100 mg/m2 divided into three consecutive days in patients with head and neck squamous cell carcinoma

Design

A two-arm parallel groups randomized trial randomized phase 2-3 by permuted block in 70 patients

Settings and conduct

This study enrolled men and women with head and neck SCC under 70 years of age. Patients underwent concurrent chemoradiation with cisplatin at Imam Khomeini Hospital Cancer Institute between 2019 and 2021. Patients with impaired Kidney functions and diabetes were excluded. Patients randomly divided into two groups after filling informed consent. Basic audiometry were checked before start of the treatment schedule. Patients received 100 mg/m2 daily continuous dose every three weeks in group A. Group B, received 100 mg / m2 cisplatin divided into three consecutive days every three weeks. Patients were pre-hydrated and post-hydrated with 2 liters of normal saline. CBC DIFF, BUN, CR tests were checked in all patients before and after chemotherapy were rechecked until normalization or the patient excluded from the study when necessary. During radiotherapy, mucositis, dysphagia, nausea, vomiting, weight loss, and tests were checked and recorded weekly. Complications were classified according to the CTCAE V.4 system.

Participants/Inclusion and exclusion criteria

Patients under 70 years of age, known case of head and neck SCC with performance status $\geq 70\%$ Definitive or adjuvant chemoradiation/ extranodal extension or positive margin Radiation dose 66-70 Gy Exclusion criteria: 1. Distant metastasis 2. Receiving previous cytotoxic drug 3. kidney disease and diabetes 4.

Intolerance to cisplatin

Intervention groups

Interventional group: cisplatin divided into 3 consecutive

Control group: cisplatin in 24 hours continuously

Main outcome variables

Mucositis, Dysphasia, Cytopenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049776N1**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **retrospective**

Last update: **2023-05-27, 1402/03/06**

Update count: **0**

Registration date

2023-05-27, 1402/03/06

Registrant information

Name

Arefeh Saeedian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2611 6394

Email address

a-saeedian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20
Expected recruitment end date
 2021-09-23, 1400/07/01
Actual recruitment start date
 2019-11-22, 1398/09/01
Actual recruitment end date
 2021-09-23, 1400/07/01
Trial completion date
 2021-09-23, 1400/07/01

Scientific title
 Complication assessment of concurrent chemoradiotherapy with 100 mg/m2 continuous dose vs 100 mg/m2 divided into three consecutive days in patients with head and neck squamous cell carcinoma , A Randomized clinical trial

Public title
 Comparison of 3-weekly administration of continuous dose cisplatin with divided dose in head and neck carcinoma

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Men and women under 70 years of age, known case of head and neck SCC with karnofsky performance status >= 70% Definitive chemoradiation or adjuvant chemoradiation in patients with extranodal extension or positive margin Radiation dose 66-70 Gy
Exclusion criteria:
 History of chemotherapy Kidney disease and Diabetes

Age
 From **18 years** old to **70 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **60**
 Actual sample size reached: **58**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Permuted block randomization 60 participants was planned by 15 random blocks of 4, each including two interventions and two controls via online system (<http://sealedenvelope.com>). In order to apply concealment, unique codes was produced by the online system. Physicians knew the codes and after enrollment the participants allocated group become visible to patients and physicians by the physician's secretary.

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

National Ethics Committee in Biomedical Research

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-12-02, 1398/09/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.220

Health conditions studied

1

Description of health condition studied

Malignant neoplasm of base of tongue

ICD-10 code

C01

ICD-10 code description

Malignant neoplasm of base of tongue

2

Description of health condition studied

Malignant neoplasm of other and unspecified parts of tongue

ICD-10 code

C02

ICD-10 code description

Malignant neoplasm of other and unspecified parts of tongue

3

Description of health condition studied

Malignant neoplasm of oropharynx

ICD-10 code

C10

ICD-10 code description

Malignant neoplasm of oropharynx

4

Description of health condition studied

Malignant neoplasm of nasopharynx

ICD-10 code

C11

ICD-10 code description

Malignant neoplasm of nasopharynx

5

Description of health condition studied

Malignant neoplasm of hypopharynx

ICD-10 code

C13

ICD-10 code description

Malignant neoplasm of hypopharynx

6

Description of health condition studied

Malignant neoplasm of pyriform sinus

ICD-10 code

C12

ICD-10 code description

Malignant neoplasm of pyriform sinus

7

Description of health condition studied

Malignant neoplasm of larynx

ICD-10 code

C32

ICD-10 code description

Malignant neoplasm of larynx

Primary outcomes

1

Description

Mucositis

Timepoint

Weekly during radiation for 7 weeks

Method of measurement

Examination

2

Description

Disphasia

Timepoint

Weekly during radiation for 7 weeks

Method of measurement

Examination

3

Description

Cytopenia

Timepoint

Weekly during radiation for 7 weeks

Method of measurement

Laboratory data

Secondary outcomes

1

Description

Disease free survival

Timepoint

18 months

Method of measurement

Phone calls. Visit at the Office

2

Description

Overall survival

Timepoint

18 months

Method of measurement

Phone calls. Visit at the Office

Intervention groups

1

Description

Intervention group: In this group, they received cisplatin every 21 days at a dose of 100 mg per cubic meter divided into three consecutive days. Chemotherapy courses were between 2 and 3 courses during the course of radiation therapy.

Category

Treatment - Drugs

2

Description

Control group: In this group, they received cisplatin every 21 days at a dose of 100 mg per cubic meter continuously in 24 hours. Chemotherapy courses were between 2 and 3 courses during the course.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital

Full name of responsible person

Arefeh Saeedian

Street address

Keshavarz Boulevard, Gharib Street

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Tehran

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Tehran

Postal code

1419733141

Phone

+98 21 6119 2587

Email

Imamhospital@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Marzieh Lashkari

Street address

Ground floor: Building No. 4, Poursina St. (north side of Tehran University), Ghods St

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3102

Email

itcenter@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Arefeh Saeedian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Tehran, at the end of Keshavarz Boulevard, Dr. Gharib Street. Imam Khomeini Hospital Complex

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Aghili

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Arefeh Saeedian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The datasets used and analyzed during the current study

are available from the corresponding (Dr Arefefeh Saeedian) upon reasonable request by two weeks.

When the data will become available and for how long

The dataset files will become available starting 6 months after publication.

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

Documents will be shared for systematic reviews only

From where data/document is obtainable

Dr Arefeh Saeedian Radiation Oncologist a-saeedian@razi.tums.ac.ir

What processes are involved for a request to access data/document

The datasets used and analyzed during the current study are available from the corresponding (Dr Arefefeh Saeedian) upon reasonable request by two weeks.

Comments