Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 >= 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 secretory.

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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Imamhospital@tums.ac.ir
Web page address

http://ikhc.tums.ac.ir/

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
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Tehran
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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
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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
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