

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The comparison of treatment outcomes between Hyperfractionated irradiation with and without concurrent chemotherapy in patients with locally advanced head and neck cancer

Protocol summary

Study aim

The comparison of treatment outcomes between hyperfractionated irradiation with and without concurrent chemotherapy in patients with locally advanced head and neck cancer

Design

The randomized clinical trial with parallel groups, double blinded with conduct on 112 cancer patients who randomly divide through random block design

Settings and conduct

The radioncology clinic of Kerman university of medical sciences is the setting of research. The patients who refer for receiving treatment services divided to two groups, hyperfractionated irradiation with and without chemotherapy

Participants/Inclusion and exclusion criteria

1. pathology diagnosis of squamous cell carcinoma of the mucosa. (Non-cutaneous) 2. The patient's cancer is locally advanced 3. The age of patients is between 18 to 75 years . 4. Karnofsky Performance Score at least 60. 5. The patient should have no evidence of distant metastasis. 6. Not receiving previous radiation and chemotherapy 7. no previous surgery on the tumor 8. The patient should not be pregnant

Intervention groups

Intervention group: receiving hyperfractionated irradiation with low dose chemotherapy control group: receiving hyperfractionated irradiation

Main outcome variables

The frequency of acute mucositis grade 3 and 4, neutropenia, neutropenic fever, nausea and vomiting, kidney and heart complications during intervention and also the survival rate after 18 months after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210404050835N1**

Registration date: **2021-07-10, 1400/04/19**

Registration timing: **prospective**

Last update: **2021-07-10, 1400/04/19**

Update count: **0**

Registration date

2021-07-10, 1400/04/19

Registrant information

Name

ahmad sholevar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of treatment outcomes between

Hyperfractionated irradiation with and without concurrent chemotherapy in patients with locally advanced head and neck cancer		Secondary Ids
		empty
Public title	Hyperfractionated irradiation with and without concurrent chemotherapy in locally advanced head and neck cancer	Ethics committees
Purpose	Treatment	<u>1</u>
Inclusion/Exclusion criteria	Inclusion criteria: The response of the patient's cancer tissue sample is of squamous cell carcinoma of the mucosa (non-skin). The patient's cancer is locally advanced. The age of patients is at least 18 years and at most 75 years. The Karnofsky Performance Score of the patient is at least 60. The patient should have no evidence of distant metastasis. Not receiving previous radiation therapy and chemotherapy Failure to perform previous surgery on the tumor The patient is not pregnant Exclusion criteria: The patient has synchronous primary lesion. Patient with squamous cell carcinoma of the scalp and neck. Presence of underlying diseases such as diabetes and hypertension, renal failure, ischemic heart disease.	Ethics committee
		Name of ethics committee
		Ethics committee of Kerman University of Medical Sciences
		Street address
		Vice-challenger of Treatment, Jomhori Eslami blvd.
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		Province
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		7618747653
		Approval date
		2021-02-15, 1399/11/27
		Ethics committee reference number
		IR.KMU.AH.REC.1399.168
Age	From 18 years old to 75 years old	Health conditions studied
Gender	Both	<u>1</u>
Phase	N/A	Description of health condition studied
Groups that have been masked	- Investigator - Outcome assessor - Data analyser	locally advanced squamous cell carcinoma of head and neck
		ICD-10 code
		C76.0
		ICD-10 code description
		Malignant neoplasm of head, face and neck
Sample size	Target sample size: 112	Primary outcomes
Randomization (investigator's opinion)	Randomized	<u>1</u>
Randomization description	In the present study, patients randomly divided to two groups based on random number sequence. The random number sequence create by SAS statistical software and patients randomly allocated to intervention and control groups according to their entrance order. The random allocation will conceal by opaque, sealed envelopes.	Description
Blinding (investigator's opinion)	Double blinded	The frequency of acute mucositis grade 3 and 4
Blinding description	According to type of intervention, patients are not blind in this study, but data analyser and outcome assessor are blind. for data analysis, intervention and control groups are labeled with A and B and outcome assessor will follow up patients based on alphabetic list of names without name of groups.	Timepoint
Placebo	Not used	7, 14,21,28, 35, 42 and 49 days after intervention
Assignment	Parallel	Method of measurement
Other design features		History and physical examination
		<u>2</u>
		Description
		The frequency of neutropenia
		Timepoint
		7, 14,21,28, 35, 42 and 49 days after intervention
		Method of measurement
		History and physical examination
		<u>3</u>
		Description
		The frequency of neutropenic fever
		Timepoint

7, 14, 21, 28, 35, 42 and 49 days after intervention

Method of measurement

History and physical examination

4

Description

The frequency of nausea and vomiting

Timepoint

7, 14, 21, 28, 35, 42 and 49 days after intervention

Method of measurement

History and physical examination

5

Description

The frequency of renal complications

Timepoint

Before intervention, 7, 14, 21, 28, 35, 42 and 49 days after intervention

Method of measurement

History and physical examination

6

Description

The frequency of heart complications

Timepoint

Before intervention, 7, 14, 21, 28, 35, 42 and 49 days after intervention

Method of measurement

History and physical examination and electrocardiogram

Secondary outcomes

1

Description

The disease-free survival rate

Timepoint

18 months after intervention

Method of measurement

The telephone follow up

2

Description

The progression-free survival rate

Timepoint

18 months after intervention

Method of measurement

The telephone follow up

3

Description

The overall survival rate

Timepoint

18 months after intervention

Method of measurement

The telephone follow up

Intervention groups

1

Description

Intervention group: receiving hyperfractionated irradiation with low dose concurrent chemotherapy. Patients in this group treating by hyperfraction radiation therapy, with a total dose of 8160 cGy in 68 fractions, with a dose of 120 cGy per fraction twice daily, with an interval of at least six hours between each fractions (according to the technique and dose that used in the phase 3 RTOG9003 trial) five days per week by Linear accelerator radiation therapy machine, with concurrent chemotherapy of low-dose Intravenous Carboplatin (equivalent to 1.5 AUC) one day weekly, for total treatment duration of 7 weeks.

Category

Treatment - Other

2

Description

Control group: receiving hyperfractionated irradiation. Patients in this group treating by hyperfraction radiation therapy, with a total dose of 8160 cGy in 68 fractions, with a dose of 120 cGy per fraction twice daily, with an interval of at least six hours between each fractions (according to the technique and dose that used in the phase 3 RTOG9003 trial) five days per week by Linear accelerator radiation therapy machine, for total treatment duration of 7 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Mohammad Hasan Larizadeh

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Radioncology department, Afzalipour hospital. Imam Khomeini highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Hasan Larizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Latest degree

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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