

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

To evaluate the feasibility and safety of hypofractionated radiotherapy in early laryngeal cancers: a phase 2 clinical trial

Protocol summary

Study aim

Determining the frequency of complete clinical response and discontinuation of treatment due to acute complications in patients with laryngeal cancer undergoing hypofractionated radiotherapy. Determining the frequency and severity of dermatitis in patients with laryngeal cancer undergoing hypofractionated radiotherapy. Determining the frequency and severity of esophagitis and voice quality in patients with laryngeal cancer undergoing hypofractionated radiotherapy.

Design

In this phase 2 clinical trial, there is a study group. The sample size is 49 people. Eligible people are selected consecutively from among people with early-stage laryngeal cancer.

Settings and conduct

This phase two clinical trial is conducted on patients with early-stage laryngeal cancer who are referred to the radiotherapy oncology department of Namazi Hospital affiliated to Shiraz University of Medical Sciences. The estimated time for conducting the study will be 1402-1403. All patients receive hypofractionated radiotherapy with a total dose of 54 Gy in 18 sessions (3 Gy per session)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Definitive diagnosis of squamous cell carcinoma of larynx based on pathology report 2. glottic lesions T1-2 3. No involvement of neck lymph nodes 4. 18 to 75 years old 5. Performance level based on ECOG, less than 3 Exclusion criteria: 1. Other malignant histologies of the larynx except scc 2. History of head and neck radiotherapy 3. Previous history of chemotherapy 4. History of diabetes or uncontrolled blood pressure 5. History of tracheostomy 6. History of laser microsurgery

Intervention groups

In the clinical trial, there is one study group in which patients with early-stage laryngeal cancer are treated with hypofractionated radiotherapy (18 sessions, 3 Gy per session)

Main outcome variables

Pathologic complete response; side effects

General information

Reason for update

Acronym

non

IRCT registration information

IRCT registration number: **IRCT20230128057262N1**

Registration date: **2023-07-21, 1402/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-21, 1402/04/30**

Update count: **0**

Registration date

2023-07-21, 1402/04/30

Registrant information

Name

Mahsa Elahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3632 4781

Email address

elahi.mahsa1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-19, 1402/04/28

Expected recruitment end date

2024-07-18, 1403/04/28

Actual recruitment start date

2022-07-19, 1401/04/28

Actual recruitment end date

2024-07-18, 1403/04/28
Trial completion date
2025-02-20, 1403/12/02

Scientific title
To evaluate the feasibility and safety of hypofractionated radiotherapy in early laryngeal cancers: a phase 2 clinical trial

Public title
Hypofractionated radiotherapy in early laryngeal cancers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of squamous cell carcinoma of the larynx based on pathology report Glottic lesions T1-2 No involvement of neck lymph nodes (N0) 18 to 75 years old Performance level based on ECOG less than 3
Exclusion criteria:
Other malignant histologies of the larynx except squamous cell carcinoma History of head and neck radiotherapy Previous history of chemotherapy Previous history of malignancy except skin BCC History of diabetes or uncontrolled blood pressure History of tracheostomy With a history of laser microsurgery

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **49**
Actual sample size reached: **49**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
nothing

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Faculty of medicine, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71937-11351

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.sums.med.rec.1401.495

Health conditions studied

1

Description of health condition studied

laryngeal cancer

ICD-10 code

C32

ICD-10 code description

Malignant neoplasm of larynx

Primary outcomes

1

Description

Pathologic complete response

Timepoint

Post operation

Method of measurement

Pathologic examination

Secondary outcomes

1

Description

Side effects

Timepoint

Weekly during intervention course

Method of measurement

Radiation therapy toxicity criteria

Intervention groups

1

Description

Intervention group: Patients with early stage laryngeal cancer are treated with hypofractionated radiotherapy with a total dose of 54 Gy in 18 sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Mohammad Mohammadianpanah

Street address

Thirty-Sixth room, Department of radiation oncology,
Namazi hospital, Namazi square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address

<http://research.sums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahsa Elahi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Rezident

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

information about main outcomes of the study

When the data will become available and for how long

six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centers

Under which criteria data/document could be used

In order to improve treatment of disease and subsequent research and with the permission of the authors

From where data/document is obtainable

Department of radiation oncology of Shiraz university of medical science

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

Sending the request in writing or by email to authors

Comments