

# 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

**City**

shiraz

**Province**

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**Postal code**

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**Phone**

+98 71 3647 4320

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**Email**

mohpanah@sums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammadhashem Hashempur

**Street address**

Deputy of research, Shiraz University of Medical  
Sciences, Zand Avenue

**City**

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**Province**

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**Postal code**

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**Phone**

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**Fax**

+98 71 3235 7282

**Email**

hashempurm@sums.ac.ir

**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

**Street address**

NO. 2

**City**

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**Province**

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71859-39799

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elahi.mahsa1992@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Mohammadianpanah

**Position**

Full Proffosor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Thiry-six room, Department of radiation  
oncology, Namazi hospital, Namazi square

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**Province**

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**Email**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mahsa Elahi

**Position**

Rezident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

Forty- second room, Department of radiation oncology, Namazi hospital, Namazi square

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**Province**

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**Postal code**

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**Phone**

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**Fax**

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**Email**

elahi.mahsa1992@gmail.com

## 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**