

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### To evaluate the efficacy and safety of adding metformin to chemoradiation of patients with squamous cell carcinoma of hypopharynx, nasopharynx, and larynx

#### Protocol summary

##### Study aim

Determination of the efficacy and safety of adding metformin to chemoradiation of patients with squamous cell carcinoma of hypopharynx, nasopharynx, and larynx

##### Design

Non-randomized clinical trial phase II without controls and without blindness

##### Settings and conduct

The eligible patients with proven diagnosis of squamous cell carcinoma of hypopharynx, nasopharynx, and larynx referring to radiation oncology department of Namazi hospital in Shiraz will be received radiotherapy (60-70 Gy in 30-35 fractions) with concurrent chemotherapy weekly. Participants (N = 25) will take metformin orally twice daily (1000 mg/day) after eating from 7 to 11 days prior chemoradiotherapy until the end of it. Toxicity score will be assessed weekly according National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE). The response criteria in spiral CT scan will be checked 12 weeks after the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include non-diabetics (FBS < 125 mg/dl and BS < 140 mg/dl); age equals or less than 18 years old; biopsy-proven squamous cell carcinoma of hypopharynx, nasopharynx, and larynx; performance status < 2. Exclusion criteria: diabetic patients; simultaneous cancer; pregnancy; distant metastasis; hypersensitivity to metformin; renal failure; liver disease.

##### Intervention groups

Patients (single group) with squamous cell carcinoma of hypopharynx, nasopharynx and larynx under treatment with concurrent chemoradiation will take metformin orally twice daily (1000 mg/day) during treatment

##### Main outcome variables

The complete response criteria in spiral CT scan

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191203045594N1**

Registration date: **2019-12-12, 1398/09/21**

Registration timing: **prospective**

Last update: **2019-12-12, 1398/09/21**

Update count: **0**

##### Registration date

2019-12-12, 1398/09/21

##### Registrant information

##### Name

Zeinab Adelpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4320

##### Email address

adelpourz@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-18, 1398/09/27

##### Expected recruitment end date

2020-03-17, 1398/12/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

To evaluate the efficacy and safety of adding metformin to chemoradiation of patients with squamous cell carcinoma of hypopharynx, nasopharynx, and larynx

## Public title

The effect of metformin on treatment of squamous cell carcinoma of neck

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patients with biopsy-proven squamous cell carcinoma of hypopharynx, nasopharynx, and larynx

### Exclusion criteria:

All patients with distant metastasis Hypersensitivity to metformin

## 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: **25**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## 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

2019-06-26, 1398/04/05

## Ethics committee reference number

IR.SUMS.MED.REC.1398.239

## Health conditions studied

### 1

#### Description of health condition studied

Malignant neoplasm of larynx

#### ICD-10 code

C32.9

#### ICD-10 code description

Malignant neoplasm of larynx, unspecified

## Primary outcomes

### 1

#### Description

The complete response

#### Timepoint

12 weeks after the intervention

#### Method of measurement

Spiral CT scan

### 2

#### Description

Toxicity

#### Timepoint

Weekly

#### Method of measurement

Common Terminology Criteria for Adverse Events (CTCAE)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patients with proven diagnosis of squamous cell carcinoma of hypopharynx, nasopharynx, and larynx receiving concurrent chemoradiation will take metformin orally twice daily (1000 mg/day) after eating from 7 to 11 days prior chemoradiotherapy until the end of it

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Namazi hospital

##### Full name of responsible person

Shapour Omidvari

##### Street address

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

**City**

Shiraz

**Province**

Fars

**Postal code**

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+98 71 3647 4320

**Fax**

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**Email**

omidvari@sums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

**Street address**

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

**City**

Shiraz

**Province**

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**Postal code**

71348-14336

**Phone**

+98 71 3235 7282

**Fax**

+98 71 3212 2430

**Email**

vcrdep@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**

Zeinab Adelpour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

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

**City**

Shiraz

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**Email**

adelpourz@sums.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shapour Omidvari

**Position**

Full Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

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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**

Zeinab Adelpour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

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**Email**

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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 the treatment of the 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 sciences

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

Sending the request in writing or by email to the authors

**Comments**