# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

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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

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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

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

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## Person responsible for scientific inquiries

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**Position**
Full Professor

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Specialist

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Radiotherapy

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## Person responsible for updating data

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**Latest degree**
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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 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**