

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of lovastatin on response rate and acute side effects of chemoradiation in locally advanced head and neck squamous cell carcinoma: A phase III randomized clinical trial

Protocol summary

Summary

This study is a phase 3 double blind randomized clinical trial that include 35 patients with locally advanced SCC of oral cavity, larynx and hypopharynx who referred for definitive chemoradiation in Tehran Cancer Institute. These patients should not have underlying liver or kidney disease and not receive any drug that interferes with metabolism of lovastatin. These patients will be randomized into 2 groups. One group receive standard chemoradiation concurrent with 80 mg daily lovastatin, divided into 4 doses, and another group receive standard treatment concurrent with placebo, in the same manner. With the initiation of possible side effects of lovastatin which include myopathy and liver toxicity, the patient will be excluded from trial. The main objective of this trial is to compare response rate between the two groups, that will be evaluated with spiral CT scan, 3 months after treatment. moreover, acute side effects of treatment such as neutropenia, anemia, thrombocytopenia, oral mucositis, dermatitis and dysphagia will be compared between the 2 groups, through physical examination and laboratory data, at the last week of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121920368N1**
Registration date: **2015-12-03, 1394/09/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-03, 1394/09/12

Registrant information

Name

Ehsan Karbasi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 7001

Email address

ekarbasi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-06-30, 1394/04/09

Expected recruitment end date

2016-03-17, 1394/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lovastatin on response rate and acute side effects of chemoradiation in locally advanced head and neck squamous cell carcinoma: A phase III randomized clinical trial

Public title

Effect of lovastatin on treatment of head and neck cancers

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: pathologic evidence of locally

advanced(T3,T4,N+) SCC of oral cavity,larynx and hypopharynx; being candidated for definitive chemoradiation; absence of underlying liver or kidney disease; not receiving any drug that interferes with metabolism of lovastatin. Exclusion criteria: initiation of possible lovastatin side effects such as myopathy and liver toxicity; inability to swallow lovastatin tablets

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 35

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

tehran university of medical sciences

Street address

6th floor,central university committee,Qods avenue corner,keshavarz boulevard

City

tehran

Postal code

Approval date

2012-09-16, 1391/06/26

Ethics committee reference number

130/1291/91/3

Health conditions studied

1

Description of health condition studied

Head and Neck Cancer

ICD-10 code

C32, C01,

ICD-10 code description

Malignant neoplasm of larynx, Malignant neoplasm of

base of tongue, Malignant neoplasm of hypopharynx

Primary outcomes

1

Description

response rate

Timepoint

3 months after treatment

Method of measurement

via CT scan

Secondary outcomes

1

Description

acute side effects of treatment

Timepoint

last week of treatment

Method of measurement

physical examination and lab tests

Intervention groups

1

Description

Intervention group: lovastatin oral tablet, 20 mg, QID, in days of treatment

Category

Treatment - Drugs

2

Description

Control group: placebo, oral tablet, QID, in days of treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Cancer Institute

Full name of responsible person

Ehsan Karbasi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences
Full name of responsible person
 Ehsan Karbasi
Street address
 Tehran Cancer Institute
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact

Name of organization / entity
 Tehran University of Medical Sciences
Full name of responsible person
 Ehsan Karbasi
Position
 Radiation Oncology Resident
Other areas of specialty/work
Street address
 Tehran Cancer Institute
City
 Tehran
Postal code
Phone
 +98 21 8868 7001
Fax
Email
 ekarbasi@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Radiation Oncology Research Center, Tehran
 University of Medical Sciences

Full name of responsible person
 Mahdi Aghili
Position
 Associated Professor
Other areas of specialty/work
Street address
 Tehran Cancer Institute, Imam Khomeini Hospital
 Complex
City
 Tehran
Postal code
Phone
 +98 21 6119 2585
Fax
Email
 aghili@tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Tehran University of Medical Sciences
Full name of responsible person
 Ehsan Karbasi
Position
 Resident
Other areas of specialty/work
Street address
 Tehran Cancer Institute
City
 Tehran
Postal code
Phone
 +98 21 8868 7001
Fax
Email
 ekarbasi@razi.tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty