Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The impact of adding lovastatin to definitive chemoradiation therapy on response rate and acute treatment related toxicity in patients with squamus cell carcinoma of head and neck

Protocol summary

Study aim
Respons rate assessment due to adding levostatin
Design
Phase II clinical trial with control arm, the groups are parallel with blinded patients and outcome assessment. Randomization was centralised and computerised with random allocation software
Settings and conduct
This clinical trial will be performed at clinical oncology ward in golestan hospital in ahwaz, eligible patients randomized in two groups, one group (control group) received standard chemoradiotherapy (70 Gy in 2Gy/fraction, 5days in week with weekly cisplatin 40 mg/m2) and another group recieve standard chemoradiotherapy plus 40mg levastatin twice a day in treatment period. All Patients will be visited weekly in treatment course to assess treatment Toxicity. 8 weeks after treatment will completed, treatment response will be assessed with CT scans and RECIST guideline.
Participants/Inclusion and exclusion criteria
All patients older than 18 with biopsy approved squamous cell carcinoma of head and neck that don't have metastatic disease, don't recieve any treatment prior chemoradiotherapy such as surgery and chemotherapy, don't use anti inflammatory drugs or Asprine more than 3 days in week, don't use any anti cuaglane drugs, fibrate, cyclosporine and OCP, don't have life expectancy less than 2years, don't have levastatin hypersensitivity and don't pregnant.
Intervention groups
One group of patients just received standard chemoradiotherapy and another group recieve standard chemoradiotherapy plus 40mg levastatin twice a day in treatment period.
Main outcome variables
Assessment of treatment response rate with adding levastatin to standard chemoradiotherapy, assessment of acute treatment related Toxicity with adding levastatin to standard chemoradiotherapy.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171204037739N1**
Registration date: **2018-03-18, 1396/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-18, 1396/12/27**
Update count: **0**
Registration date
2018-03-18, 1396/12/27

Registrant information
Name
Pari Ghadamgahi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3374 3057
Email address
ghadamgahi.p@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-05-22, 1397/03/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of adding lovastatin to definitive chemoradiation therapy on response rate and acute treatment related toxicity in patients with squamus cell carcinoma of head and neck

Public title

Levostatin eficacy and safety in treatment of squamous carcinoma of head and neck

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 18years old Biopsy confirmed squamous cell carcinoma of head and neck

Exclusion criteria:

Surgical resection of head head and neck mass Use of Anti inflammatory drug or Asprine more than 3days in week Use of anti cuaglane drugs, fibrate, cyclosporine, OCP, Hypersensitivity to Levastatin Life expectancy shorter than 2years Received chemotherapy perior chemoradiotherapy Pregnancy

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with Random allocation software and then allocation concealment with central randomization will be done.

Blinding (investigator's opinion)

Single blinded

Blinding description

All the patients that registered in trial and reaserchers, and analyzers and persons who will be assess the reasons will be blinded about who will be in case or control group just a physician who is care about patient will be know about that.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Jondishapoor University of Medical Science

Street address

Ahwaz Jondishapoor University of Medical Science, Golestan Blvd

City

Ahwaz

Province

Khouzestan

Postal code

15792_61357

Approval date

2018-01-23, 1396/11/03

Ethics committee reference number

IR.AJUMS.REC.1396.900

Health conditions studied

1

Description of health condition studied

Squamous cell carcinoma of base of tongue

ICD-10 code

C01

ICD-10 code description

Malignant neoplasm of base of tongue

2

Description of health condition studied

Squamous cell carcinoma of tongue

ICD-10 code

C02

ICD-10 code description

Malignant neoplasm of other and unspecified parts of tongue

3

Description of health condition studied

Squamous cell carcinoma of gum

ICD-10 code

C03

ICD-10 code description

Malignant neoplasm of gum

4

Description of health condition studied

Squamous cell carcinoma of floor of mouth

ICD-10 code

C04

ICD-10 code description

Malignant neoplasm of floor of mouth

5

Description of health condition studied
Squamous carcinoma of palate
ICD-10 code
C05
ICD-10 code description
Malignant neoplasm of palate

6

Description of health condition studied
Squamous cell carcinoma of other and unspecified parts of mouth
ICD-10 code
C06
ICD-10 code description
Malignant neoplasm of other and unspecified parts of mouth

7

Description of health condition studied
Squamous cell carcinoma of tonsil
ICD-10 code
C09
ICD-10 code description
Malignant neoplasm of tonsil

8

Description of health condition studied
Squamous cell carcinoma of oropharynx
ICD-10 code
C10
ICD-10 code description
Malignant neoplasm of oropharynx

9

Description of health condition studied
Squamous cell carcinoma of nasopharynx
ICD-10 code
C11
ICD-10 code description
Malignant neoplasm of nasopharynx

10

Description of health condition studied
Squamous cell carcinoma of pyriformis sinus
ICD-10 code
C12
ICD-10 code description
Malignant neoplasm of pyriform sinus

11

Description of health condition studied
Squamous carcinoma of hypopharynx
ICD-10 code
C13
ICD-10 code description
Malignant neoplasm of hypopharynx

12

Description of health condition studied
Squamous cell carcinoma of nsal cavity
ICD-10 code
C30
ICD-10 code description
Malignant neoplasm of nasal cavity and middle ear

13

Description of health condition studied
Squamous cell carcinoma of paranasal sinus
ICD-10 code
C31
ICD-10 code description
Malignant neoplasm of accessory sinuses

14

Description of health condition studied
Squamous cell carcinoma of larynx
ICD-10 code
C32
ICD-10 code description
Malignant neoplasm of larynx

Primary outcomes

1

Description
response rate
Timepoint
8 weeks after treatment
Method of measurement
CT scan for response rate

Secondary outcomes

1

Description
Treatment related acute toxicity
Timepoint
Weekly during treatment
Method of measurement
Labratory test and physical examination

Intervention groups

1

Description
Intervention group: Tablet Levastatin 40mg twice a day during treatment+standard chemoradiotherapy
Category
Treatment - Drugs

2

Description
Control group: standard chemoradiotherapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Pari Ghadamgahi
Street address
Farvardin St., Golestan Blvd.
City
Ahwaz
Province
Khouzestan
Postal code
33118_61357
Phone
+98 61 3374 3001
Email
ghadamgahi.p@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahwaz Jondishapoor University of Medical Science, Golestan Blvd.,
City
Ahwaz
Province
Khouzestan
Postal code
15794_61357
Phone
+98 61 3333 7401
Email
info@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Pari Ghadamgahi
Position
Radiation oncology resident
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Golestan hospital, Farvardin St., Golestan Blvd.
City
Ahwaz
Province
Khouzestan
Postal code
33118_61357
Phone
0089 61 33337401
Email
ghadamgahi.p@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sasan Razmjoo
Position
Associated professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Golestan hospital., Farvardin St., Golestan Blvd
City
Ahwaz
Province
Khouzestan
Postal code
33118_61357
Phone
+98 61 3374 3057
Email
razmju@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Pari Ghadamgahi

Position
Radiation oncology resident

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

Street address
Golestan hospital., Farvardin St., Golestan Blvd

City
Ahwaz

Province
Khouzestan

Postal code
33118_61357

Phone
+98 61 3374 3057

Email
ghadamgahi.p@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available