

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluation of the efficacy of atorvastatin mouthwash 1% in prevention of radiotherapy induced oral mucositis on cancer patients in tehran city.

#### Protocol summary

##### Summary

Main objectives: Oral mucositis is one of the major side effects in cancer patients who has been radiotherapied. The aim of this clinical trial is to evaluate the efficacy of atorvastatin in prophylaxis of oral mucositis induced by radiotherapy. Design : Clinical trial , double blind , placebo controlled . Setting and Conduction : 50 patients ( 18-70 years old ) that can tolerate the radiotherapy will be recruited , In group 1 patients will take atorvastatin mouthwash , four times a day for a week ; in group 2 patients will take placebo mouthwash four times a day for a week . Participants : Inclusion criteria : patient who receive radiotherapy and age more than 18 years old ; Exclusion criteria : intolerance to atorvastatin mouthwash and incorrect use of it . Intervention: Atorvastatin mouth wash & placebo outcome measures variables: stomatitis, Solid & liquid dysphagia, hemorrhagia.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201502033014N9**  
Registration date: **2015-06-04, 1394/03/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-04, 1394/03/14

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

##### Expected recruitment start date

2015-03-20, 1393/12/29

##### Expected recruitment end date

2015-11-22, 1394/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the efficacy of atorvastatin mouthwash 1% in prevention of radiotherapy induced oral mucositis on cancer patients in tehran city.

##### Public title

Evaluation of the efficacy of atorvastatin mouthwash 1% in prevention of radiotherapy induced oral mucositis.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Cancer patients between 18-70 years receiving 5-fluorouracil containing chemotherapy regimens. Exclusion criteria: Sucralfate intolerance or inappropriate use of the mouth wash

##### Age

From **18 years** old to **70 years** old

##### Gender

Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
N/A

**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

Ethics Committee , Mazandaran University of Medical Sciences

##### Street address

Iran Vice chancellor for research , Moalem Square , Mazandaran University of Medical Sciences Sari Mazandaran , Islamic Republic Of

##### City

Sari

##### Postal code

##### Approval date

2014-09-23, 1393/07/01

##### Ethics committee reference number

23

## Health conditions studied

### 1

#### Description of health condition studied

Oral mucositis

#### ICD-10 code

K12.3

#### ICD-10 code description

( موكوزيت دهاني ) زخم دهاني

## Primary outcomes

### 1

#### Description

Oral mucositis

#### Timepoint

Every 3 days

#### Method of measurement

Use of the WHO table and ruler

## Secondary outcomes

### 1

#### Description

Pain

#### Timepoint

After 1 month of intervention

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention 1 : Atorvastatin 1% mouthwas 5ml , 4 times a day for 4 week .

#### Category

Prevention

### 2

#### Description

Intervention 2 : placebo mouthwash, 5ml, 4 times a day for 4 week .

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Cancer institute, Imam Khomeini hospital ,Tehran

##### Full name of responsible person

Zahra Jahangard

##### Street address

Keshavarz BLVD

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Ahmadali Enayati

##### Street address

Vice chancellor of research, Moalem squer, Mazandaran, Sari, Mazandaran University of Medical Sciences Mazandaran University of Medical Sciences Mazandaran University of Medical Sciences Sari Mazandaran Iran, Islamic Republic Of

00981513543083

**City**

Sari

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Mazandaran 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**

Vice chancellor for research, Mazandaran University of Medical Sciences

**Full name of responsible person**

Melika Namdari

**Position**

Pharmacy student

**Other areas of specialty/work**

**Street address**

Faculty of Pharmacy, 400 Hectari, Jadeh darya, Sari Mazandaran Iran

**City**

Sari

**Postal code**

**Phone**

00981513543083 00989111251309

**Fax**

**Email**

Sh204ala@yahoo.com ; Sala@mazums.ac.ir ; Namdarimelika@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Vice chancellor for research, Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Shahram Ala

**Position**

Clinical Pharmacy specialist and member of pharmacy faculty

**Other areas of specialty/work**

**Street address**

Vice chancellor for research, Mazandaran University of Medical Sciences , Moalem Squer Sari Mazandaran Iran, Islamic republic

**City**

Sari

**Postal code**

**Phone**

+98 15 1354 3083

**Fax**

**Email**

Sh204ala@yahoo.com

**Web page address**

Sala@mazums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Faculty of Pharmacy, Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Shahram Ala

**Position**

Associated Professor of clinical pharmacy

**Other areas of specialty/work**

**Street address**

Faculty of pharmacy, Payambar azam complex, Farahabah BLVD Sari Mazandaran Iran, Islamic Republic Of

**City**

**Postal code**

**Phone**

**Fax**

**Email**

Sh204ala@yahoo.com

**Web page address**

Sala@mazums.ac.ir

**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*