# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Evaluation of the efficacy of atorvastatin mouthwash1% 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 mouthwash1% 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**
Quastionnaire

## 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 SciencesMazandaran University of Medical SciencesMazandaran 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**

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**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**

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## 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**

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## 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*