

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the Effect of Atorvastatin Gel in Non-Surgical Treatment of Peri-Implant Mucositis

#### Protocol summary

##### Study aim

Effect of Atorvastatin Gel in Treatment of Peri-Implant Mucositis

##### Design

A randomized, double blind clinical trial was performed with 2 parallel groups. phase 3 clinical trial on 54 patients. Randomization was done with a table of random numbers.

##### Settings and conduct

At first, after obtaining written informed consent from eligible patients who meet the study inclusion criteria, referring to a private office after clinical examination including determining the depth of probing and bleeding during probing, if the patients meet the clinical inclusion criteria, they are referred to a radiologist for parallel periapical radiography to determine the level of the marginal bone relative to the crest module of the implant. In the test group, the sites will be treated with mechanical debridement and then with atorvastatin 1.2% gel, and in the control group, will be treated with placebo gel. No antibiotics or anti-inflammatory drugs are prescribed after the treatment. Then the clinical parameters to check the effectiveness of 1.2% Atorvastatin gel, at the beginning (before mechanical debridement), 1 and 3 months after the study will be recorded. A custom-made acrylic stent and a periodontal probe will be used to standardize the measurement of clinical parameters.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age greater than or equal to 18 years  
2. Severe peri-implant mucositis or mild peri-implantitis  
3. Functioning implant for older and equal to one year  
Exclusion criteria 1. Regular use of anti-inflammatory drugs in the last three months  
2. Current and former smokers  
3. Pregnancy and breastfeeding  
4. Uncontrolled diabetes and immune-compromised systemic diseases

##### Intervention groups

Intervention group will be treated with mechanical debridement and 1.2% atorvastatin gel and control

group will be treated with placebo gel

##### Main outcome variables

Bleeding on Probing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220510054805N1**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

##### Registration date

2022-11-28, 1401/09/07

##### Registrant information

##### Name

Azin Khorramdel

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3384 0468

##### Email address

dr.khorramdel@iaut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-01, 1401/08/10

##### Expected recruitment end date

2023-03-01, 1401/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the Effect of Atorvastatin Gel in Non-Surgical Treatment of Peri-Implant Mucositis

**Public title**  
Evaluation of the Effect of Atorvastatin Gel in Non-Surgical Treatment of Peri-Implant Mucositis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age greater than or equal to 18 years Patients with severe peri-implant mucositis or mild peri-implantitis (presence of Bleeding On Probing ( BOP), probing depth greater than 3 mm, no soft tissue recession with or without minimal crestal bone resorption smaller than or equal to 2 mm in periapical radiography Functioning implant for older and equal to one year  
**Exclusion criteria:**

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

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

**Sample size**  
Target sample size: **54**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The selection of participants in the study will be done by a simple randomization method, individually and with a random number table tool. In this way, a number is written in front of each person's name from the client list. Then a table is designed based on the sample size of the study and we touch a number of the numbers in the table with our eyes closed. The intervention will be done with a parallel design, where the selection of the desired patient for the intervention or the control will be done randomly with a coin tool. In this way, if it is heads, gel A is used for the patient, and if it is tails, gel B is used.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participant: They will not know whether they are receiving medicine or placebo  
Researcher and therapist: In terms of packaging, color, and consistency, medicinal gel and placebo are completely similar, and each bottle is labeled with the letters A and B to distinguish it.  
Data analyzer: The data is evaluated numerically without specifying the side with gel and placebo.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University of Medical sciences Branch Tabriz

##### Street address

No. 2 of Islamic Azad University of Tabriz branch., T-way of Ahar towards Basmenj Complex., Tabriz Town

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5157944533

#### Approval date

2022-10-25, 1401/08/03

#### Ethics committee reference number

1401.198

## Health conditions studied

### 1

#### Description of health condition studied

Peri-Implant Mucositis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Bleeding on Probing

#### Timepoint

Baseline,1 and 3 months

#### Method of measurement

Periodontal Probe

## Secondary outcomes

### 1

#### Description

Probing depth

#### Timepoint

Baseline,1 and 3 months

#### Method of measurement

Periodontal Probe

### 2

#### Description

Pain On Probing

#### Timepoint

Baseline,1 and 3 months  
**Method of measurement**  
Visual Analogue Scale

## Intervention groups

### 1

#### Description

Intervention group: After initial sampling, mechanical debridement and health education, 1.2% atorvastatin gel (1.2 mg/0.1 ml) will be injected in the desired sites and the clinical parameters of the gums will be re-measured after 1 and 3 months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group : After the initial sampling, mechanical debridement and health education, placebo gel will be injected in the desired sites and the clinical parameters of the gums will be re-measured after 1 and 3 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental office

##### Full name of responsible person

Azin Khorramdel

##### Street address

Third Floor., Rush Building., Mokhaberat Square.,  
Valiasr., Tabriz Town

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5173876696

##### Phone

+98 41 3329 6007

##### Email

a\_khorramdel@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Azin Khorramdel

##### Street address

Third Floor., Rush Building., Mokhaberat Square.,  
Valiasr., Tabriz Town

#### City

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#### Province

East Azarbaijan

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#### Phone

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#### Email

a\_khorramdel@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### 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

Islamic Azad University

##### Full name of responsible person

Katayoun Mogharrab Alile

##### Position

Dental student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

No. 69, Golestan Ave., Dr Gharib Blvd., Tabriz Town

##### City

Tanriz

##### Province

East Azarbaijan

##### Postal code

۵۱۷۳۷۸۶۶۹۶

##### Phone

+98 41 3443 2402

##### Email

Katayoun.m.98@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Azin khorramdel

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Third Floor., Rush Building., Mokhaberat Square.,

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Katayoun Mogharrab Alile

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Street address**

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**Postal code**

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**Phone**

+98 41 3443 2402

**Email**

Katayoun.m.98@gmail.com

**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**

Excel software and All data will be shared after de-identification.

**When the data will become available and for how long**

From May 2023 to July 2023

**To whom data/document is available**

Dentist, responsible student, statistics consultant.

**Under which criteria data/document could be used**

Statistical analysis with spss software.

**From where data/document is obtainable**

Refer to the email address of Dr. Azin Khorramdel  
a\_khorramdel@yahoo.com.

**What processes are involved for a request to access data/document**

Send email to a\_khorramdel@yahoo.com and request data and receive them within a month.

**Comments**