

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The Effects of Systemic and Locally Azithromycin Adjunct to Scaling and Root Planning on Clinical and Microbiological Periodontal Indices in Moderate to Severe Chronic Periodontitis

#### Protocol summary

##### Summary

The aim of this study is to investigate the effects of Azithromycin (systemic and locally) on the clinical and microbiological parameters of periodontal in patients with chronic periodontitis. The double-blind, placebo-controlled clinical trial that is carried out in eighty patients who referred to the Department of Periodontology, Isfahan School of Dentistry. Main inclusion criteria were: 1) Patients with moderate to severe chronic periodontitis 2) At least twenty teeth 3) Age over 18 years. Main exclusion criteria were: 1) History of allergy to the macrolide group 2) History of antibiotic therapy within the 4 months ago 3) The lack of patient cooperation. For all patients is initially performed scaling and root planning (SRP). Oral health education is given to all patients. After one month, patients are randomly divided into four equal groups (two test groups and two control groups). Azithromycin(AZM) 250 milligram (mg) capsules, two times a day (bid), for three days will be given to a test group. In the other test group, 1% AZM gel is locally injected into the periodontal pockets in single-root teeth. Placebo capsules with the same dose and frequency will be given to a control group. In the other control group, placebo gel is injected in the same places. Clinical parameters included pocket depth (PD), clinical attachment level (CAL), papillary bleeding index (PBI), and periodontal disease index (PDI), which are recorded at baseline (before SRP), at 1, 2, 3 and 4 months after treatment. Using polymerase chain reaction (PCR), microbiological assessment of the percentage of Porphyromonas gingivalis (P.g) and Actinobacillus actinomycetemcomitans (A.a) are randomly done for 40 patients (10 patients from each group) at baseline and at 3 months after the treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201094877N10**  
Registration date: **2013-01-08, 1391/10/19**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-01-08, 1391/10/19

##### Registrant information

##### Name

Jaber Yaghini

##### Name of organization / entity

Isfahan University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1434 2136

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Public and private

##### Expected recruitment start date

2012-05-12, 1391/02/23

##### Expected recruitment end date

2013-03-09, 1391/12/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The Effects of Systemic and Locally Azithromycin Adjunct to Scaling and Root Planning on Clinical and Microbiological Periodontal Indices in Moderate to Severe Chronic Periodontitis

## Public title

The Effects of Azithromycin in the Treatment of Chronic Periodontitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1) Patient's age over 18 years 2) At least 20 native teeth 3) With moderate to severe periodontitis. Exclusion criteria: 1) With Systemic diseases that affect periodontal conditions such as: diabetes, blood disorders and diseases of immune system 2) History of antibiotic therapy within the 4 months prior to study 3) History of Allergy to the macrolide group of antibiotics 4) Smoking 5) The lack of patient cooperation 6) History of periodontal treatment during the 4 months prior to the trial 7) Pregnancy 8) Lactating females 9) Patients treated with drugs such as: Anti-acid, Warfarin and Cyclosporine 10) Alcohol use.

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

This is a prospective, double-blind, placebo-control clinical trial. Randomization method: Simple, so according to Othello, by a person who is not involved in the study, patients were divided into four groups (two test groups and two placebo-control groups). The reason of the double-blind: the researchers and patients do not know the type of medication prescribed.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee, Isfahan University of Medical Sciences

##### Street address

School of Dentistry, Isfahan University of Medical Sciences, St. Hezar Jirib, Isfahan

##### City

Isfahan

##### Postal code

81746-73461

#### Approval date

2012-05-06, 1391/02/17

#### Ethics committee reference number

10/110/5

## Health conditions studied

### 1

#### Description of health condition studied

Moderate to severe chronic periodontitis

#### ICD-10 code

k05

#### ICD-10 code description

k05.3

## Primary outcomes

### 1

#### Description

Periodontal Pocket Depth

#### Timepoint

Before the intervention, one, two, three and four months after intervention

#### Method of measurement

color coded periodontal probe (Nordent)

### 2

#### Description

Clinical Attachment Level

#### Timepoint

Before the intervention, one, two, three and four months after the intervention

#### Method of measurement

color coded periodontal probe (Nordent)

### 3

#### Description

Periodontal disease index

#### Timepoint

Before the intervention, one, two, three and four months after the intervention

#### Method of measurement

color coded periodontal probe (Nordent), radiographic

assessment, six Ramfjord selected teeth

#### 4

##### **Description**

Papillary Bleeding Index

##### **Timepoint**

Before the intervention, one, two, three and four months after the intervention

##### **Method of measurement**

color coded periodontal probe (Nordent), (Muhlemann and Saxer) classification

#### 5

##### **Description**

Porphyromonas gingivalis count

##### **Timepoint**

Before the intervention and three months after the intervention

##### **Method of measurement**

Real Time PCR - Primer Design kits

#### 6

##### **Description**

Actinobacillus actinomycetemcomitans count

##### **Timepoint**

Before the intervention and three months after the intervention

##### **Method of measurement**

Real Time PCR - Primer Design kits

## **Secondary outcomes**

#### 1

##### **Description**

Patient Compliance

##### **Timepoint**

Before and four months after the intervention

##### **Method of measurement**

Visual Analogue Scale, AlignMap

#### 2

##### **Description**

Plaque Index

##### **Timepoint**

Before the intervention, one, two, three and four months after the intervention

##### **Method of measurement**

Quigley-Hein, Turesky Modification

#### 3

##### **Description**

Oral Hygiene Status

##### **Timepoint**

Before the intervention, one, two, three and four months after the intervention

##### **Method of measurement**

Simplified Oral Hygiene Index (Greene and Vermillion)

## **Intervention groups**

#### 1

##### **Description**

Intervention group (1): scaling and root planning (SRP) plus systemic prescription of antibiotic Azithromycin; Azithromycin capsule: 250 mg (as Dihydrate), at mouth (Po), two times a day (bid) for three days; brand name: Zimexir (Exir Pharmaceutical Co.); how to use: one hour before meals or two hours after a meal, one month after SRP

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Intervention group (2): SRP plus placement of the in-situ gel 1% Azithromycin (based on Carbopol) into the periodontal pockets in single rooted teeth; twice with an interval of 20 minutes, one month after SRP

##### **Category**

Treatment - Drugs

#### 3

##### **Description**

Control group (1): SRP plus systemic prescription of placebo capsule; placebo capsule: 250 mg, at mouth (Po), two times a day (bid) for three days; drug name: Zimexir (Exir Pharmaceutical Co.); how to use: one hour before meals or two hours after a meal, one month after SRP

##### **Category**

Placebo

#### 4

##### **Description**

Control group (2):SRP plus placement of the in-situ placebo gel (Carbopol) into the periodontal pockets in single rooted teeth; twice with an interval of 20 minutes, one month after SRP

##### **Category**

Placebo

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Department of Periodontology, School of Dentistry, Isfahan University of Medical Sciences

###### **Full name of responsible person**

Dr. Ahmadreza Mogharehabet

###### **Street address**

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###### **City**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Omid Savabi

**Street address**

School of Dentistry, Isfahan University of Medical Sciences, St. Hezar Jirib, Isfahan

**City**

Isfahan

**Grant name****Grant code / Reference number**

390279

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

Yes

**Title of funding source**

Vice chancellor for research, Isfahan 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

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## Person responsible for updating data

#### Contact

## 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*