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

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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 Cyclisporine 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

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

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Isfahan

Postal code
81746-73461

Approval date
2012-05-06, 1391/02/17

Ethics committee reference number
10/110/د

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 Mogharehabed
Street address
School of Dentistry, Isfahan University of Medical Sciences, St. Hezar Jirib, Isfahan
City
Isfahan

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

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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