

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of systemic administration of azithromycin following non-surgical treatment in patients with moderate chronic periodontitis

Protocol summary

Summary

Chronic periodontitis is an inflammatory disease of the tooth supporting tissues which is caused by micro organisms residing in the subgingival bio film . This chronic inflammation will progressively destruct the periodontal ligament. The basic treatment plan is oral hygiene instruction,removal of irritation factors and scaling and root planning(SRP). The effect of SRP in treatment of chronic periodontitis has been previously proved by several studies. The purpose of this study is to evaluate azithromycin as an adjunct to SRP treatment in patients with chronic periodontitis . This study is a randomized, double blinded, placebo controlled study.Inclusion criteria: having at least 20 teeth and at least 18 years of age. exclusion criteria: pregnancy, allergy to macrolids, SRP in the last 6 months 40 individuals-divided equally into 2 groups. Intervention: administration of azithromycin only on the first day of treatment until 3 days. result: improvement in clinical signs of gingiva

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071518493N1**

Registration date: **2015-03-06, 1393/12/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-06, 1393/12/15

Registrant information

Name

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Name of organization / entity

Hamadan University of Medical Sciences, Faculty of Dentistry

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2015-02-23, 1393/12/04

Expected recruitment end date

2015-10-12, 1394/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of systemic administration of azithromycin following non-surgical treatment in patients with moderate chronic periodontitis

Public title

Azithromycin's effect on periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:non smoker patient;18 years old or more;with at least 20 teeth Exclusion criteria:pregnancy;antibiotic therapy in the last 3 months;use of any antibiotics during the study;allergy to macrolids;use of warfarin or cyclosporins;immune system insufficiency

Age

To **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Zahedan University of Medical Science

Street address

Zahedan University of Medical Science-Dr.Hesabi square

City

Zahedan

Postal code

Approval date

2015-02-08, 1393/11/19

Ethics committee reference number

6731

Health conditions studied

1

Description of health condition studied

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic pericoronitis Periodontitis: NOS complex simplex

Primary outcomes

1

Description

Pocket depth

Timepoint

pre treatment,2 weeks after treatment,1 month after treatment,3 month after treatment

Method of measurement

distance between gingiva margin to base of pocket by williams probe

2

Description

Clinical attachment level

Timepoint

pre treatment,2 weeks after treatment,1 month after treatment,3 month after treatment

Method of measurement

distance between cej to base of pocket by williams probe

3

Description

Gingival index

Timepoint

pre treatment,2 weeks after treatment,1 month after treatment,3 month after treatment

Method of measurement

by O'Leary technique

4

Description

Plaque index

Timepoint

pre treatment,2 weeks after treatment,1 month after treatment,3 month after treatment

Method of measurement

by O'Leary technique

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Administrating azithromycin 250 mg for 3 days,2 pills per day,Scaling Root Planing ,Oral hygiene instruction.

Category

Treatment - Drugs

2

Description

Control group:Administrating placebo for 3 days,2 pills per day.Scaling Root Planing,oral hygiene instructions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Gholami

Street address

Periodontology departement, Dentistry School, Mehr st

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Rafigh doost

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

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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