

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The evaluation of the effect of Azithromycine on inflammatory and fibroblastic part of Cyclosporine (CsA) induced gingival overgrowth in renal transplanted patients with and without scaling

Protocol summary

Summary

Objective: The evaluation of the effect of Azithromycine (AZM) on inflammatory and fibroblastic part of Cyclosporine (CsA) induced gingival overgrowth in renal transplanted patients with and without scaling Design: randomised controlled clinical trial, One blinded (data analyzer) Inclusion criteria: transplanted patients with systemic use of CsA; more than 18 year old; existing upper and lower 6 teeth of anterior segment; gingival overgrowth in grade 1 based on King Index; plaque index more than 10% Exclusion criteria: hypersensitivity for macrolid antibiotics; not having stable renal function; having any periodontal treatment after transplantation; local irritation in Maxiillary and Mandibular anterior teeth; Oral breathing; smoking 24 patients are randomized (randomly selection numbers` Software) in 2 groups. Group1: the patients received a 5 day Azithromycine AZM regimen without scaling (two 250 milligram capsules of AZM at first day that followed with 1 capsule in 4 days). Group2: at first visit , they will be received a professional supra and subgingival scaling with ultrasonic cavitron and will be prescribed AZM (the same way as group 1) after 2 months. The results will be evaluated in weeks 4 and 8 in group1 after prescribing AZM and in weeks 4,8,12,16 in group2 . Primary outcome variables: gingival overgrowth Secondary outcome variables: clinical crown length; gingivitis; dental plaque; probing depth

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040529321N2**

Registration date: **2017-08-15, 1396/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-15, 1396/05/24

Registrant information

Name

hamidreza baghaniaval

Name of organization / entity

sabzevar medical school

Country

Iran (Islamic Republic of)

Phone

+98 51 4465 1300

Email address

baghanih@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University Of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2011-06-22, 1390/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of Azithromycine on inflammatory and fibroblastic part of Cyclosporine (CsA) induced gingival overgrowth in renal transplanted patients with and without scaling

Public title

Effect of Azithromycine (AZM) on gingival overgrowth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: transplanted patients with systemic use of CsA; more than 18 year old; existing upper and lower 6 teeth of anterior segment; gingival overgrowth in grade 1 based on King Index; plaque index more than 10% Exclusion criteria: hypersensitivity for macrolid antibiotics; not having stable renal function; having any periodontal treatment after transplantation; local irritation in Maxiillary and Mandibular anterior teeth; Oral breathing; smoking

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomaised Controlled Clinical Trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Researches center, Tahmasbabad Crossover, Kerman

City

Kerman

Postal code

Approval date

2011-04-11, 1390/01/22

Ethics committee reference number

90/40/۱۵

Health conditions studied

1

Description of health condition studied

gingival enlargement

ICD-10 code

k06.1

ICD-10 code description

gingival fibromatosis

Primary outcomes

1

Description

Gingival enlargement

Timepoint

Before intervention, 4,8,12,16 weeks after intervention

Method of measurement

Periodontal probe

Secondary outcomes

1

Description

Gingivitis

Timepoint

Before intervention, 4, 8, 12, 16 weeks after intervention

Method of measurement

Observation, periodontal probe

2

Description

Dental plaque

Timepoint

Before intervention, 4, 8, 12, 16 weeks after intervention

Method of measurement

observation, plaque disclosing tablet

3

Description

Clinical crown length

Timepoint

before intervention, 4, 8, 12, 16 weeks after intervention

Method of measurement

Periodontal probe

4

Description

Probing depth

Timepoint

Before intervention, 4, 8, 12, 16 weeks after intervention

Method of measurement

periodontal probe

Intervention groups

1

Description

control:Drug Two 250 miligram Azithromycine capsule at first day and then one 250 miligram Azithromycine capsule daily for 4 days

Category

Treatment - Drugs

2

Description

Intervention: Scaling Drug Two 250 miligram Azithromycine capsule at first day and then one 250 miligram Azithromycine capsule daily for 4 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nephrology private center

Full name of responsible person

Dr.Jalal Azmandian

Street address

Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kerman university of medical sciences

Full name of responsible person

Dr.Arash Shahravan

Street address

Researches Center, TahmasbAbad Crossover, Kerman

City

Kerman

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, Kerman 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

Private office

Full name of responsible person

Sara beyhaghi

Position

Dentist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman Dental School

Full name of responsible person

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Position

Periodontist, Assisstant Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Private Office

Full name of responsible person

Sara Beyhaghi

Position

Dentist

Other areas of specialty/work

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Web page address

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