

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effect of local Erythromycin versus local Gentamicin on the Kristal bone lesion around the dental implant: a double-blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of local Erythromycin versus local Gentamicin on the Kristal bone lesion around the dental implant

Design

This is a double-blind randomized clinical trial, in which 30 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are the candidate for a dental implant and will refer to School of Dentistry in Mashhad City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 25 to 60 years; Candidate for dental implant
Exclusion criteria: Individuals without any teeth; Immunodeficiency; Diabetes; Inflammation around the surgery location

Intervention groups

Intervention group 1: Erythromycin antibiotic ointment 0.5% single dose on the screw cover of dental implant
Intervention group 2: Gentamicin antibiotic ointment 0.3% single dose on the screw cover of dental implant

Main outcome variables

Assessing the Kristal bone lesion around the dental implant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N262**

Registration date: **2019-02-12, 1397/11/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-12, 1397/11/23**

Update count: **0**

Registration date

2019-02-12, 1397/11/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of local Erythromycin versus local Gentamicin on the Kristal bone lesion around the

dental implant: a double-blind randomized clinical trial

Public title

Comparison of the effect of local Erythromycin versus local Gentamicin on the Kristal bone lesion around the dental implant

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 25 to 60 years; Candidate for dental implant

Exclusion criteria:

Individuals without any teeth; Immunodeficiency; Diabetes; Inflammation around the surgery location

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The apparent shape of the ointments will be perfectly the same. Therefore, patients will be unaware of the type of intervention. In addition, the drugs will be given by the third person, therefore, the physician who will examine the patients will not be aware of the intervention.

Therefore, the trial will be run as double-blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Mashhad University of Medical Sciences, Shahid Fakoori Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.090

Health conditions studied

1

Description of health condition studied

Dental implant failure

ICD-10 code

M27.69

ICD-10 code description

Other endosseous dental implant failure

Primary outcomes

1

Description

Assessing the Kristal bone lesion around the dental implant

Timepoint

Before surgery and 3 months after that

Method of measurement

Through phosphor plate radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Erythromycin antibiotic ointment 0.5% single dose on the screw cover of dental implant immediately after preparing implant

Category

Treatment - Drugs

2

Description

Intervention group 2: Gentamicin antibiotic ointment 0.3% single dose on the screw cover of dental implant immediately after preparing implant

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Dentistry

Full name of responsible person

Dr Naser Sargolzaei

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School of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Naser Sargolzaei

Position

Dental Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Naser Sargolzaei

Position

Dental Student

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Other areas of specialty/work

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Person responsible for updating data

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Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available