

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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		Name of ethics committee Ethics Committee of Mashhad University of Medical Sciences	
Public title	Comparison of the effect of local Erythromycin versus local Gentamicin on the Kristal bone lesion around the dental implant	Street address	Vice-chancellor for Research and Technology, Mashhad University of Medical Sciences, Shahid Fakoori Boulevard
Purpose	Treatment	City	Mashhad
Inclusion/Exclusion criteria		Province	Razavi Khorasan
Inclusion criteria:	Age of 25 to 60 years; Candidate for dental implant	Postal code	9138813944
Exclusion criteria:	Individuals without any teeth; Immunodeficiency; Diabetes; Inflammation around the surgery location	Approval date	2018-12-19, 1397/09/28
Age	From 25 years old to 60 years old	Ethics committee reference number	IR.MUMS.DENTISTRY.REC.1397.090
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor	Description of health condition studied Dental implant failure	
Sample size	Target sample size: 30	ICD-10 code M27.69	
Randomization (investigator's opinion)	Randomized	ICD-10 code description Other endosseous dental implant failure	
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.	Primary outcomes	
Blinding (investigator's opinion)	Double blinded	1	
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	Description Assessing the Kristal bone lesion around the dental implant	
Placebo	Not used	Timepoint Before surgery and 3 months after that	
Assignment	Parallel	Method of measurement Through phosphor plate radiography	
Other design features		Secondary outcomes empty	
Secondary Ids	empty	Intervention groups	
Ethics committees		1	
1		Description Intervention group 1: Erythromycin antibiotic ointment 0.5% single dose on the screw cover of dental implant immediately after preparing implant	
Ethics committee		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 centers1**Recruitment center****Name of recruitment center**

School of Dentistry

Full name of responsible person

Dr Naser Sargolzaei

Street address

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

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

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

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Position

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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