Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of antibiotic prophylaxis on clinical and patient reported outcome and inflammation-related indicators of oral implant therapy with guided bone regeneration.

Protocol summary

Study aim

Evaluation of the effect of antibiotic prophylaxis on clinical and patient reported outcome and inflammation-related indicators of oral implant therapy with guided bone regeneration.

Design

Clinical trial with control group, double-blind, with parallel groups, randomized, phase 3 on100 patients. A random number table was used for randomization using closed envelopes.

Settings and conduct

A total of 100 patients referred to Mashhad Dental School who are applying for implants and at the same time need a bone graft in the form of GBR will be included in this study. For blindness with the help of random number and code for each patient, a person other than the patient surgeon puts the type of intervention in the envelope. data analyzer and the Outcome assessor are blinded in this study. In all groups, one type of graft and membrane is used However, in the intervention group, in addition to routine treatment patients will also have to take 2gr of amoxicillin one hour before work. One week later, pain intensity will be assessed by the visual analog scale and bleeding, swelling and hematoma assessment check-list based on the patient's Yes or No answer.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1- An age range 20 to 50 years 2-The extent of the lesion is limited 3-No previous surgical procedures have been initiated in the specific area 4-Absence of systemic disease 5-Non smoker 6-Do not take drug interfere with the treatment process 7- Dehiscence defects in buccal surface of the implant exclusion criteria:1-Do not refer 2-Patients who are allergic to amoxicillin 3-The presence of severe infection 4- Opening the edge of the wound.

Intervention groups

Intervention group: In addition to routine treatment, patients receive 2gr amoxicillin an hour before work. control group: Patients will receive routine treatment.

Main outcome variables

Pain, Bleeding, Hematoma and swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140817018834N8**
Registration date: **2021-06-10, 1400/03/20**
Registration timing: **prospective**

Last update: **2021-06-10, 1400/03/20**
Update count: **0**

Registration date

2021-06-10, 1400/03/20

Registrant information

Name

Nahid Nasrabadi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences of Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35 1621 2623

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-13, 1400/03/23

Expected recruitment end date
2021-10-23, 1400/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of antibiotic prophylaxis on clinical and patient reported outcome and inflammation-related indicators of oral implant therapy with guided bone regeneration.

Public title
Evaluation of the effect of antibiotic prophylaxis in implant surgery with guided bone regeneration.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
• An age range of 20 to 50 years • The extent of the lesion (horizontal bone augmentation) is about one or two teeth • No previous surgical procedures have been initiated in the specific area • The patient's informed consent •Absence of systemic diseases that interfere healing process, such as diabetes • Non smoker •Do not take drugs interfere with the treatment process, such as corticosteroids • Dehiscence defects in buccal surface of the implant
Exclusion criteria:
• Do not refer for routine follow up visits • Patients who are allergic to amoxicillin • The presence of severe infection in the oral cavity • Wound opening during bone transplantation surgery
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be block. Patients will be randomly allocated in to the intervention and control groups by block randomization technique. A number of two blocks (A and B) will be considered. With the help of random numbers, a random number will be assigned to each group and this will determine the type of intervention. For blindness with the help of random number and code for each patient, a person other than the patient surgeon puts the type of intervention in the envelope. The type of intervention (use of prophylaxis or not) is recommended to the patient .
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the design of the study, it is not possible to blind the participants, principal investigator and clinic staff, and Each person's data are made available to the data analyzer and the Outcome assessor without knowing the case group or being in control.
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_Mashhad faculty of dentistry
Street address
Mashhad faculty of dentistry, Vakil Abad Blv, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Approval date
2021-05-12, 1400/02/22
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1400.035

Health conditions studied

1

Description of health condition studied
Horizontal alveolar bone defects.
ICD-10 code
k08.2
ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
pain
Timepoint
1-3-7 days after surgery
Method of measurement
The patient is asked about the amount of pain by telephone using the visual analogue scale index on the first, third, and seventh days, and the patient is asked to

rate their pain experience on a scale from 0 to 10 .

2

Description
swelling
Timepoint
1_3_7 days after surgery.
Method of measurement
On the first, third and seventh day, the patient is asked about the presence or absence of swelling. due to special conditions in COVID-19 prevalence and attracting patient involvement and cooperation, On the third day, the patient will be examined remotely by sending a full face photo.

3

Description
bleeding
Timepoint
1_3_7 days after surgery.
Method of measurement
On the first, third and seventh day, the patient is asked about the presence or absence of bleeding. due to special conditions in COVID-19 prevalence and attracting patient involvement and cooperation, On the third day, the patient will be examined remotely by sending a full face photo.

4

Description
hematoma
Timepoint
1_3_7 days after surgery.
Method of measurement
On the first, third and seventh day, the patient is asked about the presence or absence of hematoma. due to special conditions in COVID-19 prevalence and attracting patient involvement and cooperation, On the third day, the patient will be examined remotely by sending a full face photo.

Secondary outcomes

1

Description
implant survival
Timepoint
3 months after surgery
Method of measurement
Clinical and radiography examination

Intervention groups

1

Description
Intervention group: In patients who are candidates for implant placement, the guided bone regeneration treatment will be performed using one type of membrane and one type of bone graft. In this group 2 gr amoxicillin will be prescribed one hour before treatment. After surgery, amoxicillin 500 mg (Abidi) every 8 hours for 7 days and ibuprofen 400 mg every 6 hours for 5 days will be prescribed.
Category
Treatment - Drugs

2

Description
Control group: In patients who are candidates for implant placement, the guided bone regeneration treatment will be performed using one type of membrane and one type of bone graft. In this group, no prophylactic antibiotic will be prescribed before treatment. after surgery, amoxicillin 500 mg (Abidi) every 8 hours for 7 days and ibuprofen 400 mg every 6 hours for 5 days will be prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad faculty of dentistry
Full name of responsible person
Nahid Nasrabadi
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Mashhad of faculty of dentistry, Vakil Abad Blv, Mashhad, Razavi khorasan province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Deputy of Technology and Research, Qureshi building, next to Hoveyze cinema, Daneshgah Avenue.
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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
Vice Chancellor for research of 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
Nahid Nasrabadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data is related to the main consequence after unidentifiable people are shared.

When the data will become available and for how long

6 month after printing the results.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If you are to submit a article to a journal, they will be asked to receive the data.

From where data/document is obtainable

Person responsible for scientific study.
nasran@mums.ac.ir

What processes are involved for a request to access data/document

Sending an email to the given address and waiting time to receive a response less than a month.

Comments