

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The Effect of administration of Amoxicillin after Implant surgery on Bacterial colonization adjacent to Implant Surgical Site: Microbiologic Study

Protocol summary

Summary

Fifty patients are going to be selected according to the stated inclusion (20-60 years old, partial edentulous patients, at most 2 implants, non-submerged technique) and exclusion (systemic diseases, smoker patients, periodontal involved, need to bone augmentation procedures in surgical area) criteria. Provided the patients accept to participate in the study, they are assigning to test (administering Amoxicillin "500 mg" after implant surgery) and control (administering placebo after implant surgery) groups, randomly. Drugs are prescribed every eight hours for seven days. Samples are taken from the sites adjacent to the implant with a paper-point 30 minutes and one week after implant placement. Samples are then sent to microbiologic department to culture the bacteria growing in the paper-point. The changes in the bacterial colonization are going to be assessed inter-groups and intra-group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706101150N1**
Registration date: **2008-10-29, 1387/08/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2008-10-29, 1387/08/08

Registrant information

Name

Neda Moslemi

Name of organization / entity

Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 3902

Email address

nmoslemi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental faculty - Tehran University of Medical Sciences

Expected recruitment start date

2008-11-22, 1387/09/02

Expected recruitment end date

2012-01-01, 1390/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of administration of Amoxicillin after Implant surgery on Bacterial colonization adjacent to Implant Surgical Site: Microbiologic Study

Public title

The Effect of Amoxicillin on Bacterial colonization adjacent to Implant Surgical Site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- 20-60 years old patients. 2- partial edentulous patients 3- At most, two implants are inserted 4- non-submerged surgical technique Exclusion criteria: 1- Smoker patients 2- periodontal involved 3- need to perform bone augmentation procedures in surgical area 4- patients who are involved in relevant

systemic diseases

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Tehran University of Medical Sciences

Street address

Ghods Ave., Keshavarz Blv., Tehran University of Medical Sciences

City

Tehran

Postal code

99694-47166

Approval date

2008-07-01, 1387/04/11

Ethics committee reference number

7060-70-02-87

Health conditions studied

1

Description of health condition studied

Prophylactic antibiotic administration after dental implant surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

microbial colonization

Timepoint

30 minutes after surgery and 1 week after surgery

Method of measurement

Microbiologic culture

Secondary outcomes

1

Description

pain

Timepoint

One week after surgery

Method of measurement

Visual scale

2

Description

swelling

Timepoint

One week after surgery

Method of measurement

Observation (yes/no)

Intervention groups

1

Description

Intervention group: Amoxicillin administration, 500mg/8h for one week

Category

empty

2

Description

placebo administration in control group

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty

Full name of responsible person

Neda Moslemi

Street address

Ghods Ave., Keshavarz Blv., Dental Faculty, Tehran University of Medical Sciences

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Neda Moslemi

Street address

Ghods Ave., Keshavarz Blv., Dental Faculty, Tehran
University of Medical Sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Dental Faculty-Tehran University of Medical Sciences

Full name of responsible person

Neda Moslemi

Position

Periodontist / Assistant Professor

Other areas of specialty/work**Street address**

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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