

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Study of the preventive effect of doxycycline at the abutment-implant interface on crestal bone resorption and peri-implant mucositis: a randomized controlled clinical trials

Protocol summary

Study aim

The evaluation of preventive effect of doxycycline at the abutment-implant interface on crestal bone resorption and peri-implant mucositis.

Design

Double blind clinical trial was performed on 20 patients. Each person was control group of himself. so that their implants on the one side of the mandible were experimental group and the opposite side was control group. Individuals in the study were evaluated that at least two implants from the Implantium system with a length of 12 mm and a diameter of 3.8 mm are implanted in the 4th, 5th and 6th edentulous regions of the mandible, bilaterally. A technician was used to assimilate the patients crown. After the preparation of Atridox gel, the gel was placed in the Annulus and the patient crown was delivered.

Settings and conduct

Double blind clinical trial. the samples were non-randomly selected, but which side of the mouth is experimental or control group, was randomly selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: at least two implants of Implantium system (Implantium, Dentium) with a length of 12 mm and a diameter of 3.8 mm in the area of edentulous 4, 5 and 6 of the mandibular be implanted bilaterally. Exclusion criteria: Systemic diseases such as diabetes, kidney disease and osteoporosis; smoking; periodontal disease; have attached gingiva less than 2 mm; poor health

Intervention groups

Twenty patients were non-randomly selected. Each person was control group of himself. so that their implants on the one side of the mandible were experimental group and the opposite side was control group.

Main outcome variables

Bleeding on probing; probing depth; the distance from the fixture shoulder to the bone crest

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180222038827N2**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **retrospective**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Mahnaz Arshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 3471

Email address

Arshad-m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2011-04-30, 1390/02/10

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

2011-04-30, 1390/02/10

Actual recruitment end date

2014-06-24, 1393/04/03

Trial completion date

empty

Scientific title

Study of the preventive effect of doxycycline at the abutment-implant interface on crestal bone resorption and peri-implant mucositis: a randomized controlled clinical trials

Public title

Effect of doxycycline on Crestal Bone Resorption

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

People with at least 2 implantium implants (Dentium, Seoul, South Korea) The site of implant in the area of first and second premolar

Exclusion criteria:

Systemic diseases that influence on bone such as; diabetes, renal diseases and osteoporosis Smoking. Periodontal diseases Attached gingival under 2 mm Poor hygiene

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Individual randomization Randomization with software Allocation concealment with unbiased person that he was not part of study

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the Tehran University of Medical Sciences

Street address

central organization of Tehran university of medical sciences, corner of Quds street, Keshavarz boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2014-06-16, 1393/03/26

Ethics committee reference number

باتوجه به اینکه در سال ۱۳۹۳ دانشگاه تهران کد ۹۲-۰۳-۶۹-۲۳۰۳۸، نامهی اخلاقی را بصورت کد طرح داده است کد با فرمت جدید موجود نمی باشد

Health conditions studied**1****Description of health condition studied**

peri-implant mucositis

ICD-10 code

M27.62

ICD-10 code description

Post-osseointegration biological failure of dental implant

2**Description of health condition studied**

crestal bone loss

ICD-10 code

M27.62

ICD-10 code description

Post-osseointegration biological failure of dental implant

Primary outcomes**1****Description**

bleeding on probing

Timepoint

3, 6 and 12 months after the delivery of final prosthesis

Method of measurement

periodontal probe

2**Description**

probing depth in mesial and distal of implant

Timepoint

3, 6 and 12 months after the delivery of final prosthesis

Method of measurement

periodontal prob

3

Description

the measurement of fixture shoulder to the bone crest

Timepoint

3, 6 and 12 months after the delivery of final prosthesis

Method of measurement

periapical radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a half of mouth is intervention group; Doxycycline polymer with trade name of Atridox was placed in annulus space in the final prosthesis delivery time and before closing abutment screw; the evaluation of probing depth, bleeding on probing and the distance of fixture shoulder and crest of bone was done 3, 6 and 9 months after the delivery of finally prosthesis

Category

Treatment - Drugs

2

Description

Control group: the other side of mouth is control group; No drug use in Annulus space; the evaluation of probing depth, bleeding on probing and the distance of fixture shoulder and crest of bone was done 3, 6 and 9 months after the delivery of finally prosthesis.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

dental implant Center, Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Arshad

Street address

Unit 9, 3th Floor, Number 3, first Alley, Sanjabi Street, Madar Square, Mirdamad Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hosseinali Mahgoli

Street address

North Amir Abad, not reaching Hakim exit, Tehran Faculty of Dentistry, prosthesis center

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1439955991

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Dentistry

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Other areas of specialty/work
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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

All data has subscription capability

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

All people

Under which criteria data/document could be used

None

From where data/document is obtainable

Email to Dr Arshad

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

None

Comments