# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 Annulous 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**

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**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 92-03-69-23038، نامه‌ی اخلاقی را بصورت کد طرح داده است کد با فرمت جدید موجود نمی‌باشد

## 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 prothesis
**Category**
Treatment - Drugs

**2**

**Description**
Control group: the other side of mouth is control group; No drug use in Annulous 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 prothesis.
**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**
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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
**City**
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hmahgoli@tums.ac.ir
**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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## 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**
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**