Clinical Trial Protocol
Iranian Registry of Clinical Trials
19 Sep 2022

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
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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
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

Primary outcomes
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

Health conditions studied
1
peri-implant mucositis
M27.62
Post-osseointegration biological failure of dental implant

2
crestal bone loss
M27.62
Post-osseointegration biological failure of dental implant

Ethics committees
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
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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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+98 21 8835 1178
Email
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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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