Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of antimicrobial photodynamic therapy as an adjunctive to mechanical debridement in the treatment of peri-implant diseases: a randomized controlled clinical trial

Protocol summary

Summary

Aim: the purpose of present study was to assess the clinical effects of anti-microbial photodynamic therapy after closed surface scaling in the treatment of peri-implant diseases. Study design: randomized controlled clinical trial. Methods and inclusion/exclusion criteria: 15 pairs of dental implants, in 10 patients, showed clinical and radiographical signs of peri-implant diseases and located at different quadrants included in this study. In each patient, one implant randomly served as control implant and the other served as test implant. The control implants were treated with closed surface scaling only and the test implants received additionally photodynamic therapy, using light with a wavelength of 630 nm and the intensity of 2000 mw/cm2 for 120 s after application of photisensitizer in peri-implant sulcus. Clinical parameters were evaluated before and 1.5 and 3 months after treatment. Data were analyzed statistically. Interventions: closed surface scaling- photodynamic therapy. Primary outcome: clinical attachment loss-probing pocket depth.

General information

Acronym

PDT= PhotoDynamicTherapy

IRCT registration information

IRCT registration number: **IRCT201309119260N2**
Registration date: **2013-10-12, 1392/07/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-12, 1392/07/20

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

The study was self-funded by the authors.

Expected recruitment start date

2011-03-16, 1389/12/25

Expected recruitment end date

2012-07-01, 1391/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of antimicrobial photodynamic therapy as an adjunctive to mechanical debridement in the treatment of peri-implant diseases: a randomized controlled clinical trial

Public title

PDT in treatment of peri-implant diseases

Purpose

Treatment

Inclusion/Exclusion criteria

• Presence of at least two screw type titanium dental implants, in different sites, exhibiting clinical and

radiographic signs of peri-implant diseases (including peri-implant mucositis and peri-implantitis). • No implant mobility • No evidence of occlusal overload • No treatment of peri-implant diseases for the least 6 months before the study • No use of antibiotics and anti-inflammatory drugs for the 3 months prior treatment. If these drugs were taken during the study, patient would be excluded. • At least 1 year function of implants. • No pregnancy and nursing • No uncontrolled diabetes (HbA1c < 7) • In the cases that subjects had a history of periodontitis, only subjects were included if the lesions were treated at the remaining teeth and diseases was halted.

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
this is single-blind split mouth clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran Islamic Azad university, Dental branch
Street address
no 4, 10 th neyestan, pasdaran street
City
tehran
Postal code
19585-175
Approval date
2011-02-19, 1389/11/30
Ethics committee reference number
پ/250/د

Health conditions studied

1

Description of health condition studied
peri-implant diseases
ICD-10 code
K00-K14
ICD-10 code description
k05.6

Primary outcomes

1

Description
peri-implant probing pocket depth
Timepoint
before treatment, 1.5 and 3 months after treatment
Method of measurement
millimeter using williams plastic probe

2

Description
peri-implant clinical attachment loss(CAL)
Timepoint
before treatment, 1.5 and 3 months after treatment
Method of measurement
millimeter using williams plastic probe

Secondary outcomes

1

Description
peri-implant bleeding after probing(BOP)
Timepoint
before treatment, 1.5 and 3 months after treatment
Method of measurement
PBI index

2

Description
peri-implant gingival index(GI)
Timepoint
before treatment, 1.5 and 3 months after treatment
Method of measurement
gingival index

Intervention groups

1

Description
control: All implants underwent mechanical debridement, using plastic curettes followed by pocket irrigation with sterile saline. Hand instrumentation was carried out until the operator was assured that the implant surfaces were adequately debrided and no time restriction was considered. In control group, no further treatment was performed. intervention: in the PDT group, closed surface scaling followed by single-episode of photodynamic

therapy. High medium photosensitizerwas injected inside the instrumented peri-implant pocket with a thin blunt needle, as far as mucosal margin starting from the apical portion of the pocket. The photosensitizer was left in the pocket for 3 minutes. Subsequently, the light emitting device with the wavelength of 630 nm and the intensity of 2000 mw/cm2, with a special tip was placed at the depth of pocket, according to the manufacturer's instruction. The device, used in this research for implant surface irradiation, was in contact with 6 aspects per implant. Every aspect of implants was irradiated for 20 seconds, making a total of 2 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of Dr. Mohammadreza Karimi

Full name of responsible person

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Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

this study was self-funded by researchers.

Full name of responsible person

Dr. Salva Khosroshahian

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no 4, meghdad, sepah, safaie street

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qom

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

this study was self-funded by researchers.

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

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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