Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of Effectiveness of Photodynamic Therapy with Low-level Diode Laser in Nonsurgical Treatment of Peri-implantitis

Protocol summary

Summary

goal: comparison of clinical and microbial periodontal indexes changes using of low level Diode laser with and without Emundo photosensitizer material study design: clinical trail inclusion criteria: 4-6 mm pocket depth and 0.5-2 mm marginal bone loss around dental implant exclusion criteria:patient poor oral hygiene and poor cooperation sample size: 40 implants with primary peri implantitis in 20 patients Periodontal treatment comprising scaling and root planning (SRP) was accomplished for the all mouth and mechanical debridement with fiber carbon curette and air polishing with bicarbonate sodium powder was accomplished around implants. Implants were randomly divided into two groups and treated with LT (control) and PDT (test).the clinical indices were measured at baseline, 6 weeks and 3 months after treatment. Microbiological samples were taken and evaluated at baseline and 3-month follow up. Data were entered in SPSS ver. 20 and analyzed with Friedman, repeated measure of ANOVA and Mann-Whitney tests (α=0.05). time:2014-2015

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030932749N2**
Registration date: **2017-04-23, 1396/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name

mahboobeh rajabzadeh

Name of organization / entity

isfahan dental school

Country

Iran (Islamic Republic of)

Phone

+98 915 501 3649

Email address

m.rajabzadeh@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effectiveness of Photodynamic Therapy with Low-level Diode Laser in Nonsurgical Treatment of Peri-implantitis

Public title

Evaluation of Effectiveness of Photodynamic Therapy with Low-level Diode Laser in Nonsurgical Treatment of Peri-implantitis

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: 1. 4-6 mm pocket depth & 0.5-2 mm marginal bone loss 2. 2mm or more attached gingiva around implant 3. no systemic disease 4.no tobacco use 5.no use of antibiotics and drugs within previous 1month

6.no periodontal treatment except scaling and root planning within previous 2years The exclusion criteria: 1.use of alcohol or tobacco 2.pregnancy or breastfeeding 3. use of antimicrobial agents during the previous 2 months 4. history of periodontal surgery during the previous year. 5. poor oral hygiene and no cooperation 6. need to gingival graft,with out attached gingiva

Age

From **20 years** old to **67 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

isfahan medical sciences ethics committee

Street address

hezar jarib st/ isfahan

City

isfahan

Postal code

Approval date

2014-05-31, 1393/03/10

Ethics committee reference number

394383

Health conditions studied

1

Description of health condition studied

peri-implantitis or inflamatory condition around dental implant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

probing depth measurement

Timepoint

before intervention/ 3month after intervention

Method of measurement

with periodontal probe/ milimeter

2

Description

papilla bleeding index

Timepoint

before intervention/ 3month after intervention

Method of measurement

index definition/ score to bleeding on probing

3

Description

modified plaque index

Timepoint

before intervention/ 3month after intervention

Method of measurement

index definition/ plaque accumulation rate

4

Description

microbial specimen

Timepoint

before intervention/ 3month after intervention

Method of measurement

microbial culture of crevicular gingival fluid / PCR

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: Periodontal treatment comprising scaling and root planning (SRP) was accomplished for the all mouth and mechanical debridement with fiber carbon curette and air polishing with bicarbonate sodium powder was accomplished around implants. (first treatment phase) oral hygiene instruction (modified bass method) and flossing. (educational intervention) two weeks later Photo Dynamic Therapy applied. (810 nm Diode laser+ Emundo Photosensitizer) and this protocole repeated in two weeks after. *EmonDo: indocyanine green /A.R.C. laser Gmbh, Germany *Diode laser:Fox/ A.R.C. laser Gmbh, Germany

Category

Treatment - Other

2

Description
control group: Periodontal treatment comprising scaling and root planning (SRP) was accomplished for the all mouth and mechanical debridement with fiber carbon curette and air polishing with bicarbonate sodium powder was accomplished around implants. (first treatment phase) oral hygiene instruction (modified bass method) and flossing. (educational intervention) two weeks later peri implantitis treated with 810 nm Diode laser. and this protocole repeated in two weeks after. *Diode laser:Fox/ A.R.C. laser Gmbh, Germany

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
isfahan dental school

Full name of responsible person
Mahboobeh Rajabzadeh/ periodontis & implantologist

Street address
isfahan dental school/hezar jarib st/ isfahan

City
isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,isfahan University of Medical Sciences

Full name of responsible person
mahboobeh rajabzadeh

Street address
isfahan

City
isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research,isfahan 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
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Position
periodontist and implantologist/ assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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