Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical and bacteriologic comparison of scaling & root planning by ultrasonic system with or without photodynamic therapy in patients with mild to moderate chronic periodontitis

Protocol summary

Summary

Aim: The aim of this randomized clinical trial is to compare the clinical and bacteriological effects of scaling & root planing (SRP) by ultrasonic system with or without photodynamic therapy (PDT) as an adjunctive treatment. Study Design: Interventional, randomized, single blind, unicenter, no placebo, parallel clinical trial. Study samples: Patients (20-60 years old), with mild to moderate chronic periodontitis, both sex. Inclusion Criteria: Patients with mild to moderate chronic periodontitis, pocket depth of 3-6 mm and bleeding on probing at least in 3 teeth. Exclusion criteria: Pregnancy, systemic disease, antibiotic therapy, malignancy, pockets over 6mm. The patients were selected based on inclusion and exclusion criteria. In a split-mouth design study, each patient randomly (by throwing a coin) received scaling and root planing in one site of the mouth and SRP with PDT in the other site. Microbiological samples were collected from all patients at baseline, 10, 42and 90 days after treatment and also clinical parameters including pocket depth, clinical attachment loss, bleeding on probing and papillary bleeding index were measured initially and 90 days after treatment. Sample size: Twenty samples in each group, totally forty. Intervention: Utilization of scaling and root planing with or without Photodynamic therapy. Intervention Duration: Ninety days. Primary Result: Bacterial colony counting of subgingival dental plaque, pocket depth, clinical attachment loss, bleeding on probing and papillary bleeding index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013083112487N2**

Registration date: **2013-11-07, 1392/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-07, 1392/08/16

Registrant information

Name

Shirin Amini

Name of organization / entity

Khorasgan Branch, Islamic Azad University, Isfahan

Country

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and bacteriologic comparison of scaling & root planning by ultrasonic system with or without photodynamic therapy in patients with mild to moderate

chronic periodontitis

Public title
Comparison of two scaling methods with or without photodynamic therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Patients with mild to moderate periodontitis, pocket depth of 3-6 mm and bleeding on probing at least in 3 teeth. Exclusion criteria: Pregnancy, systemic disease, antibiotic therapy, malignancy, pockets over 6mm
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: The teeth in each patient were randomly selected via throwing the coin to treat by one of the treatment methods.Blindness: All the variables were measured and microbial sampling was carried out by another examiner who was blind to the selected treatment modalities for each tooth.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khorasgan Branch, Islamic Azad University
Street address
Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavaniyeh street, Eastern Jey Street, Isfahan, Iran
City
Isfahan
Postal code
81595158
Approval date
2012-04-14, 1391/01/26
Ethics committee reference number
07405/D/910303

Health conditions studied

1

Description of health condition studied
Chronic periodontitis
ICD-10 code
K05.3
ICD-10 code description
Periodontitis:simplex

Primary outcomes

1

Description
count of anaerobe and aerobe bacteria in subgingival plaque
Timepoint
at baseline and 10, 42 and 90 days after intervention
Method of measurement
dilution and culture of bacterial samples in conventional and riched solid blood agar and visual colony counting

2

Description
pocket depth
Timepoint
at baseline and 90 days after intervention
Method of measurement
measuring of pocket depth in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

3

Description
clinical attachment loss
Timepoint
at baseline and 90 days after intervention
Method of measurement
Measuring of clinical attachment loss in mm by a Williams periodontal probe (Hu-Friedy, Chicago, IL, US)

4

Description
Bleeding on probing
Timepoint
at baseline and 90 days after intervention
Method of measurement
evaluation of bleeding intensity by Bleeding Index

5

Description
papillary bleeding index
Timepoint

at baseline and 90 days after intervention

Method of measurement

evaluation of bleeding score by Papillary Bleeding Index

Secondary outcomes

empty

Intervention groups

1

Description

scaling of selected teeth in one site of the mouth for at least one min by ultrasonic device (Faraz Dentine Co, Iran)

Category

Treatment - Devices

2

Description

Scaling of selected teeth in another area of the mouth for at least 1 min and then injection of photosensitizer Toluidine blue specific for Fotosan system with special syringe of Fotosan kit that is 0.1 ml and finally irradiation of red light in 630 wavelength from LED source of Fotosan device(CMS Dental Co, Germany) for 10 seconds by special periotip

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology, Dental School,Khorasgan Branch, Islamic Azad University and Abolabbas

Full name of responsible person

Street address

Dental School, Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran and Jey Street ,Khorasgan Square,Abolabbas Clinic, Isfahan,Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice- Chancellor of Islamic Azad University Khorasgan Branch

Full name of responsible person

Esfahanian, Vahid

Street address

Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavanieh Street, Eastern Jey Street, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice- Chancellor of Islamic Azad University Khorasgan Branch

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

Dental School, KhorasganBranch, Islamic Azad University

Full name of responsible person

Amini, Shirin

Position

Assistant Professor/ DDS, MSc

Other areas of specialty/work

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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