ISRCTN07764690 https://doi.org/10.1186/ISRCTN07764690

Efficacy of adjunctive Er:YAG laser for the treatment of chronic periodontitis

Submission date
13/05/2014

Recruitment status
No longer recruiting

Registration date
22/07/2014

Overall study status
Completed

Last Edited
22/07/2014

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gum disease is a very common condition where gums are sore, swollen or infected. If severe, a condition called periodontitis can develop; this is a serious gum infection that can damage the soft tissues and destroy the jaw bone supporting the teeth. Symptoms include bad breath, gum abscesses, loose teeth and tooth loss. In the worse cases, it can even lead to serious health problems such as heart attacks and strokes. It is caused by plaque, a sticky film that is mostly made up of bacteria, that forms on the teeth. It can be removed by good oral hygiene, but it reforms quickly. If it stays on the teeth for more than one day, it can harden into a substance called tartar. Tartar is more difficult to remove and cannot be gotten rid of by brushing and flossing the teeth. There is a lot of evidence to suggest that removing plaque and tartar through a process called mechanical root debridement (a treatment that uses a number of ultrasonic and manual instruments to break up and scrape away tartar and plaque) much improves periodontal health and prevents destruction of soft tissues. The main aim of this study was to find out how well an instrument called a Erg:Yag performed when being used in combination with full-mouth subgingival (under the gums) debridement as a treatment for chronic periodontitis.

Who can participate?
Participants who are at least 18 years old and diagnosed with periodontitis

What does the study involve?
Participants are randomly allocated into one of two groups a control and a test group. Those in the test group are first treated with a full-mouth ultrasonic debridement. A week later, they are treated with the Er:YAG laser by the same operator. Patients in the control group are also treated with a full-mouth ultrasonic debridement. In this group, the right side of the mouth is treated on the first day and the left side one week later. The same ultrasonic device is used in both groups but they were manned by different operators in order to prevent treatment bias.

What are the possible benefits and risks of participating?
All diagnostic and treatment procedures are provided free of cost for all participants taking part in the trial. They are then closely monitored for any complications or relapses and treated

accordingly for a year after the initial debridement. The risks to patients are no different to those seen for the conventional treatment of the condition. This includes swelling, bleeding and pain.

Where is the study run from?
University Complutense, Madrid (Spain)

When is the study starting and how long is it expected to run for?
April 2007 to January 2011

Who is funding the study?
University Complutense, Madrid (Spain) and Kavo Dental S.L (Spain)

Who is the main contact?
Professor Mariano Sanz
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Clinical efficacy of subgingival debridement with adjunctive Er:YAG laser in chronic periodontitis patients. A randomised clinical trial.

Study objectives
To test the efficacy of a full mouth ultrasonic subgingival debridement protocol combined with the application of Er:YAG laser only in those probing pocket depths initially moderate-deep (≥4. 5mm), compared to conventional ultrasonic debridement without the laser application

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Trials Committee of the University Hospital (Comité de Ensayos Clínicos del Hospital Universitario), San Carlos, Madrid, C.P.-C.I., February 2006, ref. 13/368-E.

Study design
A 12-month, single-masked, parallel group clinical trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Initial to moderate chronic periodontitis

Interventions
Non-surgical periodontal therapy. Two different protocols were used:
Test group: A full-mouth session of scaling and root planing (SRP) with ultrasounds plus the use of the Er:YAG laser in initial pockets with a probing pocket depth ≥4.5 one week later.
Control group: two session of SRP one week apart, one in the right side of the mouth and the other in the left.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in probing pocket depth (PPD): PPD was recorded with an electronic periodontal probe (Florida Probe®, Gainesville, FL, USA) using a controlled force of 25 gr and measured to the closest 0.5 mm. This electronic probing system has two description modes, the graphic display and the data mode. In the graphic display, it automatically segments PPDs in three categories: shallow (1-4 mm), moderate (5-6 mm) and deep (≥7 mm). In the data mode, the moderate category, however, starts when PPDs ≥ 4.5 mm. In this investigation PPDs ≥ 4.5 mm in the data mode (equivalent to ≥ 5 mm in the graphic display) were selected for laser application in the test group.

Secondary outcome measures
1. Changes in the proportion of moderate-deep pockets (% PPD≥4.5)
2. Changes in the proportion of open pockets (% PPD≥4.5+positive bleeding on probing)
3. Changes in gingival recession (REC): the distance between the gingival margin (GM) and the cemento-enamel junction (CEJ) or the margin of the restoration. A negative value was given when the GM was located coronal to the CEJ.
4. Changes in clinical attachment level (CAL): This was calculated as the addition of PPD plus REC.
5. Changes in bleeding on probing (BOP): Measuring presence/absence of bleeding within 15 s after probing.
6. Changes in plaque index: Absence/presence of plaque after staining with erythrosine (Plac Control®, Dentaid, Barcelona, Spain).

Both primary and secondary outcome measurements were carried out at baseline, 3, 6 and 12 months.

Overall study start date
01/04/2007

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Males and females over 18 years old.
2. Diagnosis of chronic periodontitis based on the presence of at least 4 teeth per quadrant with PPD≥4.5 mm and radiographic bone loss between 30-50% in more than 30% of teeth.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Systemic diseases requiring antibiotic prophylaxis or other systemic medication that could affect the subjects clinical response.
2. Pregnant women or in breastfeeding period.
3. Periodontal treatment within the last 12 months or systemic antibiotic intake in the last 3 months.
4. Not willing to participate in the study

Date of first enrolment
01/04/2007

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
Spain

Study participating centre
Master de Periodoncia. Estomatología III
Madrid
Spain
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Sponsor information

Organisation
Faculty of Dentistry, Complutense University of Madrid (Spain)

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Sponsor type
University/education

ROR
https://ror.org/02p0gd045

Funder(s)

Funder type
University/education

Funder Name
ETEP (Aetiology and Therapy of Periodontal Diseases) Research Group, University

Funder Name
Complutense, Madrid (Spain)

Funder Name
Kavo Dental, S.L. Madrid (Spain).

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration