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The benefits of Nd:YAG laser in the treatment of gum disease in an adult population

Submission date 07/06/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/06/2022	**Overall study status** Completed	
Last Edited 11/10/2023	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims

Periodontitis is a severe gum infection that can lead to tooth loss and other serious health complications. Periodontitis (per-e-o-don-TIE-tis), also called gum disease, is a serious gum infection that damages the soft tissue and, without treatment, can destroy the bone that supports your teeth.

The aim of this trial is to evaluate in stage III/IV periodontitis the clinical efficacy of the adjunctive use of Nd:YAG laser, applied with two different protocols, to full-mouth scaling and root planing (FMS), compared to FMS alone.

The application of neodymium-doped: yttrium aluminium garnet (Nd:YAG) laser irradiation as a tool in nonsurgical periodontal (gum) therapy is due to the anti-inflammatory and antimicrobial irradiation properties, which might enhance the effectiveness of traditional periodontal therapy. Full-mouth scaling includes the removal of hard and soft tissue deposits from the root of a periodontally-affected tooth.

Who can participate?

The study involved participants recruited from a pool of patients initially presented to the Periodontal Department, 401 Athens Military Hospital, Athens, Greece, seeking periodontal treatment. Every patient diagnosed with severe chronic generalized periodontitis was enrolled in the study.

What does the study involve?

Participants will be randomly allocated to receive either treatment as usual, or in addition one or two laser therapy sessions.

What are the possible benefits and risks of participating?

All patients received thorough periodontal treatment. There were no risks for the patients involved in the study.

Where is the study run from?

401 Athens MIlitary Hospital (Greece)

When is the study starting and how long is it expected to run for?
July 2014 to October 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
252/31-07-2014

Study information

Scientific Title
Adjunctive Nd:YAG laser irradiation in the treatment of stage III/IV periodontitis. A 12-month, randomized, controlled trial.

Study objectives
Adjunctive Nd:YAG laser irradiation in the treatment of III/IV periodontitis ameliorates the results of non-surgical periodontal therapy as a monotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 31/07/2014, Ethical Committee of the National and Kapodistrian University of Athens (2 Thivon Street, Athens, Goudi, Greece 11527; +30 2107461203; vanag@dent.uoa.gr), ref: 252 /31-07-2014

Study design
Double-masked parallel-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adjunctive Nd:YAG laser in non-surgical periodontal therapy

Interventions
The study includes two test and one control group with a parallel design. The 3 patient groups consist of 60 patients, who initially will receive non-surgical periodontal treatment in two consecutive sessions, under local anesthesia. After completion of non-surgical therapy, the 60 patients will consecutively be randomized into 3 treatment groups (Laser 1, Laser 2, control).

For both test groups, an Nd:YAG Laser (1064 nm) will be utilized. For Laser 1 group, laser therapy will be performed once, 1 week after scaling and root-planing. For Laser 2 group, laser therapy will be performed 1 week after scaling and root-planing and be repeated 1 week later, with identical laser settings.

Randomization was performed using a blocked randomization list stratified by sex and smoking status with a block size of 6. The list was created using the Sealed Envelope online tool.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Assessed before treatment initiation and at 6 weeks, 3-, 6- and 12 months post-treatment:
PD, CAL, gingival recession (GR), full-mouth plaque scores (FMPS), full-mouth bleeding scores (FMBS), simplified gingival index (GI).
All clinical measurements were taken using a manual probe. PD, CAL and GR were performed at six sites per tooth, while FMPS, GI and FMBS were
recorded at four sites per tooth. Third molars were excluded from the measurements.

Key secondary outcome(s))
Immediately after treatment, sixty (60) questionnaire forms were provided to each subject. Patients were asked to fill out the questionnaire at the end of the first week of the completion of treatment. A visual analogue scale was used to assess patients' perception of pain, sensitivity discomfort, swelling, bleeding and acceptance of the protocol during and after treatment. They were also asked to answer if they should suggest the treatment to a friend. This scale ranged from 0 to 10. Subjects marked a point on a 10-cm-long uncalibrated line with the negative

extreme response (0) on the left end and the positive extreme response (10) at the right end. Additionally, the numbers of analgesic tablets taken were assessed.

Completion date
14/10/2020

Eligibility

Key inclusion criteria
1. 35 - 65 years-old
2. Presence of at least 16 teeth
3. Periodontitis with PD ≥5 mm with bleeding on probing (BOP) in at least 30% of the teeth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
65 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Poorly controlled diabetes
2. Autoimmune diseases
3. Genetic disorders
4. Bone metabolic diseases
5. Bisphosphonate drugs
6. Drug-induced gingival overgrowth
7. Tumours or other oral pathology
8. Pregnant or lactating women
9. Antibiotic use for any purpose within 3 months before entering the study

Date of first enrolment
24/11/2015

Date of final enrolment
14/10/2020

Locations

Countries of recruitment
Greece

Study participating centre
401 Athens MIlitary Hospital
Mesogeion Avenue 138 and Katechaki Str.
Athens
Greece
11525

Sponsor information

Organisation
National and Kapodistrian University of Athens

ROR
https://ror.org/04gnjpq42

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	16/02/2023	17/02/2023	Yes	No
Results article	10/10/2023	11/10/2023	Yes	No
Basic results	05/01/2023	05/01/2023	No	No