ISRCTN11340841 https://doi.org/10.1186/ISRCTN11340841

Is combined laser treatment effective for patients with periodontal disease?

Submission date
21/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
10/01/2025

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Periodontitis (gum disease) is an infection of the gums that can lead to tooth loss. In recent years, many types of dental lasers have been used for the non-surgical treatment of periodontal diseases. However, it remains unclear whether the combined application of lasers is effective as an adjuvant treatment for chronic periodontitis. The purpose of this study is to compare the use of combined treatment with Er: YAG laser and low-level diode laser, to treatment with the Er: YAG laser only, to treatment with the low-level diode laser only, and to traditional treatment of periodontal diseases in a Chinese population.

Who can participate?
Chronic periodontitis patients aged between 35 and 70 years in Beijing.

What does the study involve?
This study will use a split-mouth design, where patients will receive multiple different treatments to different sections of the mouth to control for the difference between each patient. Each quadrant (right upper jaw, left upper jaw, left lower jaw, right lower jaw) will be randomly allocated to receive one of four treatment groups: combined treatment with Er: YAG laser and low-level diode laser; treatment with the Er: YAG laser only; treatment with the low-level diode laser only; and traditional treatment. Clinical periodontal examinations were evaluated at baseline, 3 months, and 6 months.

What are the possible benefits and risks of participating?
In addition to traditional periodontal therapy, participants will receive free laser treatment in the experimental quadrants. Side effects of the treatments may include a small amount of pain in the gum for one or two days after the treatment.

Where is the study run from?
Department of Stomatology of Beijing Chao-Yang Hospital (China)

When is the study starting and how long is it expected to run for?
From August 2021 to July 2022

Who is funding the study?
Beijing Municipal Science & Technology Commission (China)

Who is the main contact?
Prof. Zhou
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Combined application of Er:YAG and low level diode lasers in treatment of periodontitis: A split-mouth, randomized controlled trial

Study objectives

Combined application of Er:YAG and Low level diode lasers may provide more effective treatment than conventional scaling and root planing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/09/2021, Ethics Committee of the Beijing Chao-Yang Hospital (No.8 GongRenTiYuChangNanLu, Chao Yang District, Beijing, P.R.China 100020; +86-10-85231484; no email address available), ref: 2021-Sci-558

Study design
Interventional single-centre single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Moderate or severe periodontitis

Interventions
The study will use a split-mouth design, with each patient serving as their own control. Each quadrant (right upper jaw, left upper jaw, left lower jaw, right lower jaw) will be randomly allocated into four test groups (A group, B group, C group) or control group (D group). A group will receive Er:YAG laser plus low level diode laser treatment (LLLT), B group will receive Er:YAG laser only, C group will receive LLLT only, while the control quadrants will receive traditional treatment only.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Probing depth (PD) measured using periodontal probing at baseline, 3 months, and 6 months
2. Clinical attachment level (CAL) measured using periodontal probing at baseline, 3 months, and 6 months

Secondary outcome measures
1. Bleeding index (BI) measured using periodontal probing at baseline, 3 months, and 6 months
2. Plaque index (PLI) assessed by an examiner using a scale of 0 to 3 (where 0= No plaque, 1=

Cannot see plaque but plaque can be detected with probe, 2= Moderate plaque can be seen, and 3= Lots of plaque can be seen) at baseline, 3 months, and 6 months

Overall study start date
01/08/2021

Completion date
11/07/2022

Eligibility

Key inclusion criteria
1. Aged 35-70 years
2. Minimum of 20 teeth (4 per quadrant)
3. It is clinically diagnosed as extensive stage III-IV periodontal disease: the heaviest site of interproximal attachment loss is ≥5 mm, radiologic bone loss extends to 1/3 of the root and above, PD ≥ 6mm, vertical bone absorption ≥3 mm, cumulative bone resorption >30%
4. Good general health

Participant type(s)
Patient

Age group
Adult

Lower age limit
35 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Received periodontal treatment within the previous 6 months
2. Received systemic antibiotic therapy within the previous 6 months
3. Suffered systemic diseases that could influence therapy outcome (e.g. diabetes mellitus, blood disease)
4. Pregnant

Date of first enrolment
01/12/2021

Date of final enrolment
05/01/2022

Locations

Countries of recruitment
China

Study participating centre
Beijing Chao-Yang Hospital
No.8 GongRenTiYuChangNanLu
Department of Stomatology
Capital Medical University
Chao Yang District
Beijing
China
100020

Sponsor information

Organisation
Beijing Chao-Yang Hospital

Sponsor details
No.8 GongRenTiYuChangNanLu
Department of Stomatology
Capital Medical University
Chao Yang District
Beijing
China
100020

Sponsor type
Hospital/treatment centre

Website
http://www.bjcyh.com.cn

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and Technology Commission

Alternative Name(s)
Science and Technology Commission of Beijing Municipality, Beijing Municipal Science & Technology Commission, Adminitrative Commission of Zhongguancun Science Park, Beijing Municipal Science and Technology Commission, Beijing Municipal Science & Technology Commission, , ,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer- reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The trial individual data were collected and are maintained by the Department of Stomatology, Beijing Chao-Yang Hospital, Capital Medical University, Beijing, China. The corresponding author takes full responsibility for the acquisition, management, analysis, and interpretation of data for this trial. The individual trial data will not be made available to the public but may be available for researchers upon their reasonable request to xuanzhou2004@hotmail.com. Each participant of the trial will give informed consent before enrolment. The data will become available three months after the trial end date. The trial data will be stored in the SPSS documents.

SPSS statistical package (Version 18.0; SPSS Inc.) was used for data analyses. The distributions of all outcome values were examined using the Kolmogorov–Smirnov normality test. Since they were all normally distributed, baseline characteristics between four quarters were compared using one way ANOVA test. Pairwise comparisons within each treatment groups (3 months vs. baseline and 6 months vs. baseline) were performed by least significant difference (LSD) method. The level of significance was set at $p < 0.05$

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/08/2024	10/01/2025	Yes	No