

Is laser treatment effective for patients with periodontal disease?

Submission date 08/07/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/07/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/08/2019	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In recent years, dental lasers have been used for the non-surgical treatment of periodontal (gum) diseases. However, it is unclear whether lasers are effective at improving treatment for chronic periodontitis (inflammation of the gums). This study aims to determine whether the use of a laser called Er:YAG is more effective than the traditional treatment of scaling and root planing (SRP) for periodontal diseases in a Chinese population.

Who can participate?

Chronic periodontitis patients aged between 35-70 in Beijing

What does the study involve?

The study design involves splitting the patient's mouth into two sides - a test side and a control side. Teeth were randomly allocated into the test side or the control side i.e. if teeth on the left hand side were allocated test group, the right hand side will be the control group. Participants in the test group will receive laser treatment and traditional SRP treatment, whereas participants in the control group will receive traditional SRP treatment only. To determine the effectiveness of the treatment, participants will have a clinical examination involving assessment of their probing depth, clinical attachment level, bleeding index and plaque index. For the test and control groups, treatment will occur at 0 months, 3 months and 6 months. Treatment will occur after a clinical examination.

What are the possible benefits and risks of participating?

A benefit of participating is that patients will receive traditional periodontal treatment, along with free laser treatment for those in the test group. There is the risk of a small amount of pain in the gum for 1-2 days after treatment.

Where is the study run from?

Department of Stomatology, Beijing Chao-Yang Hospital, Beijing

When is the study starting and how long is it expected to run for?

March 2015 to December 2017

Who is funding the study?

1. The Beijing Science and Technology Committee (China)
2. National Natural Science Foundation of China (China)

Who is the main contact?

Prof. Zhou

xuanzhou2004@hotmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Xuan Zhou

ORCID ID

<https://orcid.org/0000-0003-2522-1283>

Contact details

Department of Stomatology, Beijing Chao-Yang Hospital, Capital Medical University, Chao Yang District
Beijing
China
100020

Additional identifiers

Protocol serial number

Z151100004015100

Study information

Scientific Title

Efficacy of Er:YAG laser on chronic periodontitis as an adjunctive non-surgical treatment: a split-mouth randomized controlled study

Acronym

Er:YAG laser in Periodontal Treatment

Study objectives

Er:YAG laser combined with conventional scaling and root planing (SRP) may provide more effective adjunctive treatment than SRP alone

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Beijing Chao-Yang Hospital, 14/11/2014, No: 2014-Sci-157

Primary study design

Interventional

Study design

Interventional single-blinded single centre randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Moderate or severe chronic periodontitis

Interventions

Using a split-mouth design, two quadrants (one quadrant from each jaw) were randomly allocated to either the test or control group. The quadrants in the test group received Er:YAG laser (ERL) plus scaling and root planing (SRP) treatment, while the quadrants in the control group received SRP only.

Intervention Type

Other

Primary outcome(s)

Periodontal probing was used to measure the following at the baseline, after 3 months and after 6 months:

1. Probing depth (PD)
2. Clinical attachment level (CAL)

Key secondary outcome(s)

The following were measured at the baseline, after 3 months and after 6 months:

1. Bleeding index (BI) assessed through periodontal probing
2. Plaque index (PLI) assessed by an examiner using a scale of 0 to 3 with the following definitions:
 - 0: No plaque
 - 1: Cannot see plaque but plaque can be detected with probe
 - 2: Moderate plaque can be seen
 - 3: Lots of plaque can be seen

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Aged 35-70 years
2. Minimum of 16 teeth (4 per quadrant)
3. At least one site with probing depths (PD) ≥ 4 mm in each quadrant, with bleeding on probing
4. Good general health
5. Non-smoker

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

27

Key exclusion criteria

Possible participants were excluded if they 1) had received periodontal treatment within the previous 6 months; 2) had received systemic antibiotic therapy within the previous 6 months; 3) had suffered systemic diseases that could influence the outcome of therapy, such as diabetes mellitus or blood disease; 4) were pregnant; or 5) were smokers.

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

01/03/2015

Date of final enrolment

30/04/2017

Locations

Countries of recruitment

China

Study participating centre

Department of Stomatology, Beijing Chao-Yang Hospital, Capital Medical University

No.8 GongRenTiYuChangNanLu, Department of Stomatology, Beijing Chao-Yang Hospital, Capital Medical University, Chao Yang District

Beijing

China

100020

Sponsor information

Organisation

Beijing Chao-Yang Hospital, Capital Medical University

ROR

<https://ror.org/01eff5662>

Funder(s)

Funder type

Not defined

Funder Name

the Beijing Science and Technology Program Fund

Funder Name

the National Natural Science Foundation of China

Results and Publications

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 responsibilities for the acquisition, management, analysis, and interpretation of data for this trial. The trial individual data will not be made available to the public but may be available for researchers upon their reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2019	09/08/2019	Yes	No
Basic results		04/01/2019	15/01/2019	No	No