

# Is laser treatment effective for patients with periodontal disease?

<b>Submission date</b> 08/07/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/07/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/08/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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

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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

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

**Study design**

Interventional single-blinded single centre randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**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 measure**

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)

**Secondary outcome measures**

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

**Overall study start date**

01/11/2014

**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)  $\geq 4$  mm in each quadrant, with bleeding on probing
4. Good general health
5. Non-smoker

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

27

**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

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# Sponsor information

## Organisation

Beijing Chao-Yang Hospital, Capital Medical University

## Sponsor details

No.8 GongRenTiYuChangNanLu, Department of Stomatology,

Beijing Chao-Yang Hospital, Capital Medical University, Chao Yang District

Beijing

China

100020

## Sponsor type

Hospital/treatment centre

## Website

<http://www.bjcyh.com.cn/>

## 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

**Publication and dissemination plan**

Intending to publish in the Journal of Clinical Periodontology in 2019.

**Intention to publish date**

01/02/2019

**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?
<a href="#">Basic results</a>		04/01/2019	15/01/2019	No	No
<a href="#">Results article</a>	results	01/05/2019	09/08/2019	Yes	No