ISRCTN18400416 https://doi.org/10.1186/ISRCTN18400416

# Is laser treatment effective for patients with periodontal disease?

**Submission date**
08/07/2018

**Recruitment status**
No longer recruiting

**Registration date**
11/07/2018

**Overall study status**
Completed

**Last Edited**
09/08/2019

**Condition category**
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

### Primary study design
Interventional

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |