

# Periodontitis Vascular Dysfunction

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>25/02/2014   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>25/02/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>18/04/2017       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Moderate to severe periodontitis (PD) has been associated with a 20% increased risk of heart disease. Gum Disease may directly affect arteries wall structure, impair their dilatation capacity (ability to increase blood flow) and predispose to atherosclerosis (build up of fat). The nature of this association, however, has not yet been established. Treatment of periodontitis may also cause a transient state of systemic inflammation (swelling) with increase of concentrations of specific blood proteins (called acute phase proteins). This inflammatory state represents the body response to the local therapy and could affect blood vessels in the body. This study aims to understand better the possible impact if any, of periodontal disease (gum disease) on cardiovascular risk and general health.

### Who can participate?

Adults over the age of 18 who have moderate to severe PD.

### What does the study involve?

Participants either receive an intensive periodontal therapy or a control (fake therapy). Participants are asked to attend 15 visits to the study centre over 24 months. Participants are assessed for changes in acute phase proteins using non-invasive high resolution ultrasound scans of the arm and change in the thickness of the carotid arteries assessed by ultrasounds. Participants also may have a cycle of ischemia of their arm and its consequences on blood vessels.

### What are the possible benefits and risks of participating?

Participants may benefit from improvement in their periodontal condition. There are no notable risks with participating.

### Where is the study run from?

UCL Eastman Dental Institute And Hospital (UK)

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

April 2013 to December 2019

### Who is funding the study?

University College London (UK)

Who is the main contact?  
Dr Francesco D'Aiuto

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Francesco D'Aiuto

**Contact details**  
University College London, Gower Street  
London  
United Kingdom  
WC1E 6BT  
-----  
f.daiuto@ucl.ac.uk

## Additional identifiers

**Protocol serial number**  
14996

## Study information

**Scientific Title**  
Intensive treatment for periodontal disease: A model of and therapy for inflammatory vascular dysfunction

**Study objectives**  
The possible aetiological role of infections on the development and progression of cardiovascular diseases has attracted greater attention over the last twenty years. Individuals with periodontitis present with a modest but statistically significant increased risk of vascular events compared to controls.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
London Queen Square Research Ethics Committee, 19/11/2012, ref: 06/Q0512/107

**Study design**  
Randomised; Interventional; Design type: Treatment

**Primary study design**  
Interventional

**Study type(s)**

## Treatment

### Health condition(s) or problem(s) studied

Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

### Interventions

Current interventions as of 18/04/2017: Participants are randomly allocated to one of two groups. Participants are asked to attend 15 visits, including a screening visit, baseline visits, and visits for their treatment.

Intensive periodontal treatment (IPT) group receive an intensive treatment consisting of mechanical debridement of the diseased dentition in a single session (4-6 hrs).

Control periodontal therapy (CPT): Participants receive a control therapy consisting of oral hygiene instructions, supragingival mechanical instrumentation and polishing.

Participants may also be randomised into have remote ischemic preconditioning or a matched placebo.

Previous interventions:

IPT and CPT, Individuals included into the intervention study will be randomized to two different periodontal therapy regimens: CPT or IPT. Patients in the IPT group will receive an intensive treatment consisting of mechanical debridement of the diseased dentition in a single session (4-6 hrs). Local anaesthesia will be used as necessary.

Control group patients (CPT) will receive oral hygiene instructions, supragingival mechanical instrumentation and polishing.

### Intervention Type

Other

### Phase

Phase II/III

### Primary outcome(s)

Current primary outcome measure as of 18/04/2017:

Common carotid intima media thickness (c-IMT) is measured using an ultrasound at baseline, 12 and 24 months.

Previous primary outcome measures:

C-IMT; Timepoint(s): 12 Months, 24 Months

### Key secondary outcome(s)

Current secondary outcome measures:

1. Brachial artery flow-mediated dilatation (FMD) is measured using a blood pressure cuff at baseline, 24 hours and 1 week after periodontal treatment.
2. Pulse-wave velocity is assessed at baseline, two, six, 12, 18 and 24 months after periodontal treatment
3. Blood inflammatory markers are measured using blood tests at baseline, two, six, 12, 18 and 24 months after periodontal treatment
4. Oxidative stress is assessed at baseline, two, six, 12, 18 and 24 months after periodontal

treatment

5. Masticatory function is assessed at two time-points.

Previous secondary outcome measures:

1. Biomarkers; Timepoint(s): Every 6 months for 24 months
2. Clinical Periodontal Measures; Timepoint(s): Every 12 months
3. FMD; Timepoint(s): Every 6 months up to 24 months
4. PVW; Timepoint(s): Every 6 months up to 24 months

**Completion date**

01/12/2019

## **Eligibility**

**Key inclusion criteria**

1. Subject must be > 18 years
2. Subject must have moderate to severe PD (at least 30 periodontal pockets >4mm with Bleeding on Probing)
3. Subject must have voluntarily signed the informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Female subject is pregnant or lactating or of childbearing and not using acceptable methods of birth control
2. Subject is on chronic treatment (i.e., two weeks or more) with specific medications known to affect periodontal status (phenytoin or cyclosporine) within one month of baseline visit
3. Subject knowingly has HIV or Hepatitis
4. Subject has limited mental capacity or language skills such that simple instructions cannot be followed or information regarding adverse events cannot be provided
5. Subjects on chronic antibiotic therapy or who require antibiotic coverage for periodontal procedures
6. Subjects had a course of periodontal therapy in the preceding 6 months

**Date of first enrolment**

01/04/2013

**Date of final enrolment**

01/12/2017

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Eastman Dental Institute**

256 Gray's Inn Road

London

United Kingdom

WC1X 8LD

**Sponsor information****Organisation**

University College London (UK)

**ROR**

<https://ror.org/02jx3x895>

**Funder(s)****Funder type**

Industry

**Funder Name**

Johnson & Johnson Consumer Services (EAME) Ltd

**Funder Name**

NIHR University College London Hospitals Biomedical Research Centre; Grant Codes: F189

**Results and Publications**

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date